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IN THE

Supreme Court of the United States

October Term, 1980

E. R. SQUIBB & SONS, INC.,

Petitioner,

vs.

JUDITH SINDELL, MAUREEN ROGERS, ABBOTT LABORATORIES, ELI LILLY & COMPANY, REXALL DRUG COMPANY, and THE UPJOHN COMPANY, INC.,

Respondents.

PETITION FOR A WRIT OF CERTIORARI TO THE SUPREME COURT OF CALIFORNIA.

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PETITION FOR A WRIT OF CERTIORARI TO THE SUPREME COURT OF CALIFORNIA.

Questions Presented.

1. Whether a state violates the Due Process and Equal Protection Clauses of the Fourteenth Amendment, and unduly burdens interstate commerce in violation of the Commerce Clause, by the adoption of a concededly novel rule under which virtually an entire industry can be compelled to defend in the courts of the state, subject to the assessment of damages against *each* member of the industry, *every time* a plaintiff (1) claims harm from a fungible product manufactured by that industry, and (2) claims inability to identify the actual maker of that product; the question here is whether virtually all the members of an industry can be compelled by a single state to defend at all under such a rule.

2. Whether, assuming that a state can otherwise constitutionally compel litigation under the rule described in the previous paragraph, there is nevertheless inherent in the rule such elements of arbitrariness in the assessment of damages as to render the rule unconstitutional on that ground alone, because of impairment of rights in contravention of the Due Process and Equal Protection Clauses of the Fourteenth Amendment, and the placing of an undue burden on interstate commerce in contravention of the Commerce Clause.

List of Parties.

In its decision, the Supreme Court of California ruled on the claims of two separate individuals, who brought suits for personal injuries in different California counties, but whose cases were consolidated for purposes of appeal only. Numerous named and fictitious defendants were included in the complaints filed by Ms. Sindell and Ms. Rogers, but it appears that most of them were never served, or were dismissed.

All of the parties appearing in the litigation at the California Supreme Court level are identified in the caption of this petition. Ms. Sindell and Ms. Rogers are individuals and were plaintiffs at the trial court level, while the remaining parties are pharmaceutical manufacturers, and were named as defendants in one or both of the Superior Court cases.

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To the Honorable Warren E. Burger, Chief Justice of the United States, and to the Honorable Associate Justices of the United States Supreme Court:

Petitioner, E. R. Squibb & Sons, Inc., respectfully prays that a Writ of Certiorari be issued to review the judgment and opinion of the Supreme Court of California entered in this proceeding on March 20, 1980.

Opinions Below.

The opinion of the Supreme Court of California is reported at 26 Cal.3d 588; 163 Cal.Rptr. 132; 607 P.2d 924 (1980), and is reproduced in the Appendix to this petition.

The Supreme Court decision was preceded by an opinion of the California Court of Appeal, Second Appellate District, Division Three, which was originally certified for publication and reported in the Advance Sheets at 85 Cal.App.3d 1, 149 Cal.Rptr. 148 (1978). The opinion of the Court of Appeal is included in the Appendix. However, under California law, the opinion was vacated when the California Supreme Court granted hearing, and was withdrawn from publication, so that it will not appear in the permanent volume of the California Official Reports. Such an unpublished vacated opinion has no force or effect.

Jurisdiction.

The judgment of the Supreme Court of California sought to be reviewed was dated March 20, 1980. A petition for rehearing, duly filed, was denied by an order dated May 7, 1980. The jurisdiction of this Court is invoked under 28 U.S.C. § 1257(3).

Constitutional Provisions Involved.

The Fourteenth Amendment provides in pertinent part:

> "No State .... shall .... deprive any person of life, liberty, or property, without due process of law; nor

deny to any person within its jurisdiction the equal protection of the laws."

Article I, Section 8, provides that the Congress shall have power, *inter alia*,

"To regulate Commerce with foreign Nations, and among the several States, and with the Indian Tribes."

Statement of the Case.

1. The court below adopted an industry-wide solution for what it conceived to be an industry-wide problem. For purposes of this petition, we adopt the characterization of the problem made by the court below, to wit:

Beginning in 1941, the pharmaceutical industry produced and marketed diethylstilbesterol (DES), a synthetic compound of a female hormone. The number of producers of DES was approximately 200 (App. 31). The drug had multiple uses. One of these uses, commencing with FDA authorization in 1947, and terminating upon FDA order in 1971, was the prevention of miscarriage in pregnant women (App. 2). An estimated 1.5 million to 3 million pregnant women took the drug for this purpose (App. 6). The drug is not claimed to have caused significant ill effects in such women.

But ill effects have been claimed by daughters of these women (DES daughters), in consequence of ingestion of DES by their mothers during pregnancy. The court referred to a student Comment for estimates that "[h]undreds, perhaps thousands" of such daughters suffer from adenocarcinoma, a form of cancer, and that a much larger number suffer from adenosis, a nonmalignant condition characterized as vexatious and possibly dangerous (App. 6). DES daughters have brought numerous suits throughout the country against pharmaceutical firms. Because the alleged ill effects of DES are manifested only in the daughters, and

then only after a "minimum latent period of 10 or 12 years" (App. 2), it is commonly impossible for a plaintiff daughter to identify the producer of the DES ingested by her mother, and commonly impossible for a defendant firm to prove that its own DES was *not* ingested by the mother.

The court's solution of the problem was to proclaim a rule, concededly unique in American jurisprudence, that "[e]ach defendant will be held liable for the proportion of the judgment represented by its share of [the appropriate] market unless it demonstrates that it could not have made the product which caused plaintiff's injuries." (App. 27). The court deliberately left undefined what it meant by the appropriate market. (App. 28). It may be added that the court was sharply divided, three of its seven members dissenting. (App. 29-40).

2. We turn now to the two cases that are the subject of this petition. Sindell, claiming to be a DES daughter who had suffered cancer of the bladder and adenosis, brought suit in the California Superior Court against 11 pharmaceutical firms, including the petitioner, and also against 100 "Does." Demurrers by petitioner and others were sustained by reason of the plaintiff's failure (and conceded inability) to identify the particular defendant whose DES had been ingested by her mother (App. 4-5). The California Court of Appeal, Second Appellate District, reversed the judgment of dismissal (App. 41-64), on grounds subsequently rejected by the California Supreme Court (App. 1-40). Under the California procedure, the judgment of the Supreme Court was in form also a reversal of the judgment of the Superior Court, upon the novel ground previously indicated (App. 65-66).

The *Rogers* case was essentially similar, and was brought against largely the same parties, including the petitioner. *Rogers* differs from *Sindell* essentially in this one feature:

after demurrers by petitioner and some of the other defendants were sustained, the complaint was amended to allege that another of the named defendants, Eli Lilly and Company, was the maker of the DES taken by plaintiff's mother. The *Sindell* and *Rogers* cases were consolidated for purposes of appeal, and received similar dispositions in the Court of Appeal, which concluded that the other defendants should be liable notwithstanding the new allegation that Eli Lilly and Company was the source of the DES (App. 41-64). The California Supreme Court, applying its novel compensation rule in both cases, held that if Rogers does not succeed in proving her allegation concerning Eli Lilly and Company, she will be able, like Sindell, to recover from all the defendants. The Supreme Court of California entered similar judgments in the *Sindell* and *Rogers* cases (App. 65-66).

3. We now discuss the time and manner in which the federal issues were presented below. As noted, the trial court sustained petitioner's demurrer, which had been grounded on plaintiff's failure to allege that petitioner was the source of the DES ingested by her mother. When the California Court of Appeal sustained the complaint despite such failure, petitioner argued, in its brief submitted to the California Supreme Court, that this was in violation of its rights under the Due Process and Equal Protection Clauses of the Fourteenth Amendment. (App. 86-88) The California Supreme Court referred to this constitutional argument with apparent favor (App. 14), but then rendered an opinion in which it advanced a concededly novel basis of liability. Petitioner made timely filing with the California Supreme Court of a petition for rehearing, in which argument was made that the court's unique rule was in contravention of the Due Process and Equal Protection Clauses of the Fourteenth Amendment, and unduly burdened interstate commerce in contravention of the Commerce Clause

(App. 67-84). This was petitioner's first opportunity to raise these points. See, e.g., *Brinkerhoff-Faris Trust & Savings Co. v. Hill*, 281 U.S. 673, 677-78 (1930). The petition for rehearing was denied without opinion (App. 85).

REASONS FOR ALLOWANCE OF THE WRITS.

The court below proceeded on the assumption that if a fungible product caused harm to a significant number of persons, then it is fair to assume that a firm with, say, a 10 per cent share of the appropriate market caused harm to 10 per cent of the persons in that market who suffered such harm. From this point, avowedly building on a student Comment, the court concluded that, if an injured plaintiff is unable to identify the firm that made the product, then it would be "reasonable" to hold all defendants jointly liable to the plaintiff, permitting contribution in amounts proportionate to the firm's market share (App. 26). "[U]nder the rule we adopt," said the court, "each manufacturer's liability for an injury would be approximately equivalent to the damages [it actually] caused." (App. 27).

The court, petitioner submits, was blind to the practical implications of its new rule. The assumption that approximate equivalence would be achieved is illusory; indeed, the rule would be so arbitrary and unfair in the distribution of burdens as to raise constitutional issues on that ground alone, as is observed in the second of the questions presented. The court's reliance on the ordinary litigation process to achieve its desired end would create crushing litigation burdens, not just for the pharamaceutical industry, but for many other industries similarly situated—*e.g.*, makers of pesticides, herbicides, paints, dyes, food additives and preservatives, and a wide range of chemicals—makers of goods that are fungible and that produce, or are alleged to produce, delayed effects (or possibly undelayed effects) in the nature of genetic damage, sterility, cancer, and the like. These burdens would be so devastating that, regardless of possible outcome, for a state to compel persons to defend under the new rule would violate the Due Process and Equal Protection Clauses of the Fourteenth Amendment, and place an ex-

cessive burden on interstate commerce in contravention of the Commerce Clause.

Added urgency is lent to this case by the fact that an approach somewhat similar to *Sindell*, with similar practical consequences, is apparently beginning to emerge in a few other jurisdictions.

I.

Petitioner May Not Constitutionally Be Compelled to Defend at All under the Sindell Rule.

A. *The finality of the judgment.* The state judgment sought to be reviewed here is final within the meaning of 28 U.S.C. § 1257 despite the fact that, on the remand contemplated by the decision below, petitioner may conceivably win ultimate vindication on grounds other than those set forth in this petition. The state judgment is final because it denied petitioner its constitutional right to be free from the need to defend at all in the California courts.

The problem of what constitutes a final judgment under Section 1257 has occasioned difficulty over the years. See *Cox Broadcasting Corp. v. Cohn*, 420 U.S. 469, 476-87 (1975). But the Court has left no doubt whatever that a state judgment is final within the meaning of Section 1257 if in contravention of a federal claim to be free from the need to defend in a state court, notwithstanding the possibility that the defendant might ultimately prevail in proceedings on the merits in such court. Clear holdings to this effect include *Shaffer v. Heitner*, 433 U.S. 186, 195 n.12 (1977) (constitutional objection to exercise of state court jurisdiction founded solely on presence of property within state; if objection is sound "there should be no trial at all"); *American Motorists Insurance Co. v. Starnes*, 425 U.S. 637, 642 n.3 (1976) (constitutional objection to state venue statute as violative of Equal Protection Clause); *Michigan Central*

RR v. Mix, 278 U.S. 492 (1929) (constitutional objection to trial in state court as excessive burden on interstate commerce in violation of Commerce Clause); *Harris v. Washington*, 404 U.S. 55, 56 (1971) (state order requiring trial despite claim of double jeopardy); *Local 438 Construction & General Laborers' Union, AFL-CIO v. Curry*, 371 U.S. 542 (1963) (trial in state court in contravention of claimed pre-emptive effect of federal labor legislation); *Mercantile National Bank v. Langdeau*, 371 U.S. 555, 557-58 (1963) (trial in state court in contravention of claim that federal statute conferred privilege of trial in a different venue).

In the last-cited case, the Court said that it "serves the requirement of finality in 28 U.S.C. § 1257 to determine now in which state court appellants may be tried rather than to subject them . . . to long and complex litigation which may be for naught if consideration of the preliminary question of [federal statutory] venue is postponed until the conclusion of the proceedings." 371 U.S. at 558.

B. *Bringing virtually the entire industry before the court*. Under *Sindell*, every suit would be against virtually the entire industry. Plaintiffs will have an obvious incentive to join as defendants all who can be reached through long-arm service. The named defendants will also have an obvious incentive to implead all other members of the industry who can be reached through long-arm service.[1] Indeed, the court mentioned the possibility of such impleader under California law. (App. 27).

The court placed the aggregate number of DES producers at 200 (App. 31). Presumably not every single producer would be brought in. But it must be noted that the amounts involved are large. In *Sindell* the plaintiff is asking for $1

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[1]*See, e.g., American Motorcycle Ass'n v. Superior Court*, 20 Cal.3d 578, 578 P.2d 899, 146 Cal.Rptr. 182 (1978).

million in compensatory damages, and $10 million in punitive damages (App. 4). *Sindell* is typical in this regard, and there are many comparable cases pending. Whether the burden of bringing in the small producers is on plaintiffs or defendants, it should not be assumed that a significant number of the smaller producers will be spared, if they are subject to long-arm service or even only arguably subject to long-arm service.[2]

C. *The extraordinary complexity of the trial issues.* Trials under the new rule would be severely burdensome because the diversity and complexity of the issues would be compounded by the presence of the large number of defendants. It should not be assumed that common factual questions would predominate in such cases. Certainly there would be some common questions: whether DES did in fact cause the condition complained of, and the matter of the plaintiff's damages. But that just about exhausts the list.

On the crucial issue of whether individual defendants should be subject to liability, the questions will be diverse rather than common. It must be emphasized that strict liability is *not* the rule for cases of this sort.[3] The Restatement (Second) of Torts, which has undoubtedly been the major single influence in the development of product liability, expressly suggests an *exemption* from strict liability for

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[2]The fact that the only defendants liable would be those who sold in the relevant market (a concept the court left undefined) is not likely to have a substantial ameliorating effect in terms of reducing the number of defendants. Whether the relevant market is national or regional, one whose interest would be served by bringing in additional producers would presumably err on the side of "safety," effecting service in possibly doubtful cases, with the incidental consequence of precipitating disputes on the sufficiency of local contacts to sustain long-arm jurisdiction.

[3]There is of course strict liability when a particular batch has been defectively made. The reference in the text is to strict liability when complaint is made of ill consequences from an entire product line.

"new and experimental drugs . . . notwithstanding a medically recognized risk," if they show promise of being "useful and desirable", and if warning is given when appropriate.[4] This suggestion has been sedulously followed by the courts, after some initial confusion.[5] Indeed, petitioner, is not aware of a single instance. in which the suggestion has been rejected.

In DES and like cases, liability can be imposed only upon proof of fault. How does a plaintiff establish the requisite fault? *Inter alia,* he or she alleges that the defendants did not adequately test the product or that they unreasonably relied on tests conducted by others; alleges that the defendants did not adequately warn of possible dangers; alleges that the defendants did not adequately monitor use of the product, with the result that they missed early warning signals, which might have led to additional testing, or more specific warnings, or other corrective action; and alleges that the defendants marketed the product by means of negligent or fraudulent misrepresentations. Precisely such allegations were made in *Sindell* and *Rogers*; indeed, such allegations are boiler-plate in product liability suits against pharmaceutical firms.

Obviously, allegations of this kind pose factual issues that may vary widely from one defendant to another. Marketing practices commonly differ. Some defendants may have played a role in development of the drug; others may be mere licensees—and conduct unreasonable in the one

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[4]Restatement (Second) of Torts § 402A, Com. *k* (1965). The three dissenting judges in *Sindell* were fearful that the majority's new rule constituted a practical inroad on this exemption because of the rule's inhibiting effect on the "dissemination of new drugs." (App. 37).

[5]*See, e.g., Ortho Pharmaceutical Corp. v. Chapman*, 388 N.E.2d 541, 545-48 (Ind. App. 1979); *Basko v. Sterling Drug, Inc.*, 416 F.2d 417, 425-26 (2d Cir. 1969).

class may be reasonable in the other. Still other differences in legal obligations may turn on the resources available to the individual firm. Surely, on the crucial issue of monitoring and appropriate follow-up action (an issue that is commonly central in such cases), it is at least arguable that the weakest firms should not be required to measure up to standards appropriate for the most powerful, and conversely that the most powerful should not be allowed exoneration upon a showing of compliance with standards appropriate only for the weakest.

Most issues of diverse character come readily to mind. It is likely, as already noted, that there would be numerous challenges to the adequacy of long-arm jurisdiction, with no two cases exactly alike. Inevitably there would be disputes over what constitutes the relevant market, and what constituted a particular firm's share of that market in the relatively distant past when DES was ingested by plaintiff's mother; these are issues regarding which virtually all the defendants would have sharply-conflicting interests, and resolution of such issues be time-consuming.

The complexity of these issues would be compounded by the presence in every case, as defendants, of virtually all the members of the industry.[6]

D. *Consolidation of cases not a practical solution.* These problems could not be alleviated by consolidation of cases for trial. These are not instances of a common disaster, like an airplane crash, in which individual cases can be removed to the federal courts with a view to transfer under 28 U.S.C. § 1407 to a single district for pre-trial proceedings involving the two or three key defendants whose liability is typically determinative. In DES and like cases, there is

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[6]Concerning the possibility that California may yet move to strict liability in this area, see note 8 *infra*.

no predicting the incidence of litigation; and consolidation would be of little help in any event. Indeed, consolidation could greatly complicate matters. Assume consolidation of the cases of two DES daughters whose mothers ingested DES five years apart. The conduct of individual defendants that may have been reasonable at the beginning of the five-year period may have been unreasonable at the end—and vice versa. From this point of view, the multiplication of plaintiffs in a consolidated trial would create new nightmares of complexity.

E. *The potential for other industries.* The decision below has a crushing potential for a wide range of American industries. Indeed, the California Supreme Court indicated a *general* concern with how to deal with "advances in science and technology [leading to the creation of] fungible goods which may harm consumers and which cannot be traced to any specific producer" (App. 24). The difficulty of tracing the fungible product to the maker is increased if the alleged ill effects of the product are long delayed, as with DES. But there may be comparable difficulty in tracing even when the ill effects are not long delayed. Consider alleged harm, within a period of a few months, from a common food preservative produced by a number of different makers, consumed during that period in bread produced by different makers. Incidentally, under the theory of the court below, all *possible* makers of the ingested bread will presumably be subject to suit along with all *possible* makers of the preservative.

It is common knowledge that claims of ill effect through genetic damage, sterility, cancer, and the like, are constantly made regarding a wide variety of fungible products. Earlier, petitioner mentioned in this connection pesticides, herbicides, paints, dyes, and food additives and preservatives.

The list can surely be expanded, and has a potential for future growth.

The parallel between the makers of pharmaceuticals and the makers of these other products is so obvious as not to require elaboration, except for one point. Petitioner has observed that an important (but not exclusive) reason why mass trials will be so burdensome in the case of the pharmaceutical industry is that liability can be founded only upon fault, with the factual questions varying from one defendant to another. The same difficulty will be encountered in the case of these other industries. Strict liability has unmistakably emerged in cases where the product was defectively made, in the sense of deviating from specifications, or from otherwise identical units of the same product line. All other defects (real or alleged) are loosely denominated design defects, and as to these the general tendency has been to require a showing of fault.[7] California may be moving toward strict liability in this area,[8] but if so it has little

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[7]*See, e.g., Volkswagen of America, Inc. v. Young*, 272 Md. 201, 321 A.2d 737 (1974) (and cases cited therein). A recent report of the Department of Commerce made the point less equivocally, stating: "No court, in spite of some loose language that has been used, has imposed strict or absolute liability on manufacturers for products which are unreasonably unsafe in design." U.S. Department of Commerce, Model Uniform Product Liability Act, comments following § 104, reprinted in 44 Fed. Reg. 62714, 62723-24 (1979).

[8]*See Barker v. Lull Engineering Company, Inc.*, 20 Cal.3d 413, 573 P.2d 443, 143 Cal.Rptr. 225 (1978). The significance of this decision is unclear, for reasons that there is no space to elaborate here. Suffice it to say that the Department of Commerce Report, *supra* note 7, although specifically citing *Barker* in other contexts, 44 Fed. Reg. at 62722, 62724, apparently did not take the case as standing for strict liability. Here two points may be made about *Barker*: (1) If it portends strict liability in design defect cases, the factual issues will be simplified, but the stakes of the individual defendants will be vastly increased, making litigation under the *Sindell* market-share rule possibly more burdensome. (2) *Barker* should not in any event be understood to portend strict liability in cases involving new drugs, in view of the weighty policy reasons against such liability advanced in the Restatement and apparently universally accepted by the courts.

company—and the larger issue presented by this petition is not what will happen in California but what will happen throughout the nation if *Sindell* is permitted to stand. As will be seen, rulings somewhat comparable to *Sindell* are beginning to emerge in other jurisdictions in DES cases (p. 20 *infra*).

The question is not whether persons suffering the type of harm here under discussion should go unrecompensed when unable to identify the maker of the deleterious product. Statutory solutions are clearly feasible. The feasibility of a purely judicial solution that is workable and fair is less obvious; in any event, the judicial solution evolved below is constitutionally intolerable.

F. *The voidness of the judgment below under the Fourteenth Amendment.* It is submitted that the rule promulgated by the Court below contravenes the Due Process and Equal Protection Clauses of the Fourteenth Amendment. Petitioner's argument in this regard falls into two parts.

1. *The Due Process Clause: International Shoe.* The first argument is under the Due Process Clause, and involves the implications of *International Shoe Co. v. Washington*, 326 U.S. 310 (1945), and its progeny. In recent years the Court has emphasized that *International Shoe* reflects, *inter alia*, a concern "that the States through their courts, do not reach out beyond the limits imposed on them by their status as coequal sovereigns in a federal system." *World-Wide Volkswagen Corp. v. Woodson*, 100 S.Ct. 559, 564 (1980). The "limits" operate with special force on the power of a state to compel litigation within its borders. Illustrative is the repeated insistence of the Court that, wholly irrespective of considerations of litigation convenience, local contacts that suffice to support application of the substantive law of the state against a particular person may not suffice to com-

pel that person to *litigate* within the state in the very same controversy.[9]

Also reflecting these "limits" is the understanding that *International Shoe* is concerned, not only with the identity of the parties who may be compelled to defend in the local courts, but also with the character of the *issues* that may properly be raised against such parties. Thus, as recognized in *International Shoe* itself, 326 U.S. at 317, one sufficiently present for other purposes may not be suable on an out-of-state claim.

The present case presents the important question whether a jurisdictional presence sufficient to warrant resolution of the local issues raised by that presence is also sufficient to warrant injection into the litigation of non-local issues on the scale implicit in the *Sindell* rule. California is not simply imposing a local solution upon a local problem. It is difficult to characterize as a local solution the summoning to California of virtually all the members of a nation-wide industry, in case after case, to answer for conduct that is essentially national in character, and heavily regulated by the national government at that. And it is difficult to characterize as a local solution a compensation scheme so cumbersome and expensive — so fraught, in economic parlance, with transaction costs — as to promise profound consequences for whole national industries, in terms of pricing and in terms of a possibly crippling effect on all but the most powerful members of those industries.

As the court below recognized, the problem of the person unable to identify the source of an allegedly dangerous prod-

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[9]See *Shaffer v. Heitner*, 433 U.S. 186, 215 (1977); *Kulko v. Superior Court*, 436 U.S. 84, 98 (1978); *Hanson v. Denckla*, 357 U.S. 235, 254 (1958); *cf. World-Wide Volkswagen Corp. v. Woodson*, 100 S.Ct. 559, 565-66 (1980).

uct, manufactured in fungible form by a nation-wide industry, is a nation-wide problem. The court's scheme for dealing with that problem would operate nationally, with devastating national consequences. Again, the question under *International Shoe* is whether such a scheme and the issues implicated in it may be injected into litigation against companies otherwise amenable to suit in California in traditional litigation arising out of their activities within the state. We do not challenge California's jurisdiction over petitioner; we challenge California's competence to put such jurisdiction to the use contemplated by *Sindell*. Petitioner submits that this case, at the least, is as significant as any in which the Court has considered the ramifications of *International Shoe*.[10]

2. *Burdensomeness per se*. The burdensomeness of the new California rule presents a due process issue apart from *International Shoe*, and it also presents an equal protection issue. Petitioner is aware that it is generally difficult to claim constitutional detriment from procedural burdensomeness per se, but this case poses the interesting question whether California has crossed the forbidden line. The smaller producers cannot practicably defend in the multiple and complex litigation inherent in the California scheme.

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[10]It may perhaps be questioned whether *International Shoe* is properly in issue inasmuch as no objection was made below to service. But there was no occasion to make such objection. If *Sindell* is allowed to stand, and the case is remanded to the trial court, the defendants will be in a position to invoke *International Shoe* in light of the extraordinary new posture of the trial issues after the decision below. Disputation on the point in the California courts presumably would be futile, since the decision below would constitute the law of the case—but that would not prevent ultimate presentation of the *International Shoe* issue to this Court. Such a protracted procedure would be wasteful, and destructive of the claimed federal right of the petitioner to be free from the compulsion to defend in the state courts. *International Shoe* is here now, because the decision below necessarily raises the issue of compatibility with the broad principles underlying *International Shoe*.

At this point a word may be hazarded about actual litigation costs. The expenditure of $50,000 in defense of a single party in a products liability suit is not uncommon.[11] It will conservatively be assumed that a defense in the complex type of suit now under discussion will not exceed $50,000. The defense of 100 suits could thus cost $5 million, with $10 million a more plausible figure.

In short, the smaller producers (and some who are not so small) have been placed in an impossible position. Is this constitutionally tolerable? The Court has declared that " 'within the limits of practicability' . . . a State must afford to all individuals a meaningful opportunity to be heard if it is to fulfill the promise of the Due Process Clause." *Boddie v. Connecticut*, 401 U.S. 371, 379 (1971) (Harlan, J.). See also *Brinkerhoff-Faris Trust & Savings Co. v. Hill*, 281 U.S. 673, 682 (1930) ("some reasonable opportunity"). So far, the concern of the Court with this problem has not focused on the issue of litigation expenses as such, except in the case of indigents. See, *e.g.*, *Boddie v. Connecticut, supra* (civil litigation; Due Process Clause); *Griffin v. Illinois*, 351 U.S. 12 (1956) (criminal litigation; Due Process and Equal Protection Clauses).

Petitioner submits that the California Supreme Court has succeeded in doing what heretofore might have been thought implausible; it has brought to the fore the question of the pertinence of these precedents for small or even medium-sized business enterprises. The relief given in the case of indigents has been to require the state to absorb the expenses. But in the indigent situations the expenses were inevitable. Here the expenses are not inevitable. There is

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[11]Testimony of the General Counsel of Wyeth Laboratories, *Supplemental Hearings before the Subcommittee on Health and Environment of the Committee on Interstate and Foreign Commerce*, 94th Cong., 2d Sess., June 28, 1976, Serial No. 94-113, at p. 112.

no need for anyone to assume them. All that is needed is a pronouncement by this Court that fastening such expenses upon the smaller producers is intolerable under the Due Process Clause, or the Equal Protection Clause, or both. This would not operate to close the door to relief for persons harmed by the unidentifiable makers of fungibles. Rather, it would clear the way for development of more rational compensation plans, less laden with transaction costs.[12]

G. *The burden on interstate Commerce, in contravention of the Commerce Clause.* This Court has consistently held that a defendant may not be compelled to litigate in a state when the effect of the litigation would be to unduly burden interstate commerce, even though there was a sufficient jurisdictional presence for purposes of the Due Process Clause. *Denver & R.G.W.RR v. Terte*, 284 U.S. 284 (1932); *Michigan Central RR v. Mix*, 278 U.S. 492 (1929); *Atchison, T. & S.F. RR v. Wells*, 265 U.S. 101 (1924); *Davis v. Farmers' Cooperative Equity Co.*, 262 U.S. 312 (1923). The Court has never cast a shadow on these cases, and their continued vitality has been assumed by some of our most distinguished federal judges. See *Scanapico v. Richmond, F. & P. RR*, 439 F.2d 17, 25-28 (2d Cir. 1970)

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[12]Your petitioner is not pleading poverty. Clearly, petitioner has standing to raise all the points in this petition not peculiarly affecting the smaller producers. Hence, insofar as jurisdiction may turn upon standing, there is no lack of jurisdiction to consider the issue posed by the smaller producers. Assuming (but not conceding) that petitioner lacks independent standing to raise this issue, the Court may wish to take account of the following in determining the appropriateness of passing upon the issue: (1) whether, in a case that raises fundamental constitutional questions about a procedural device for repeatedly summoning to court virtually an entire industry, it would be desirable to scrutinize the procedural device in its individual parts rather than as a whole; and (2) whether, considering that the burden of this petition is largely the unconstitutionality of requiring virtually an entire industry to defend, it would be anomalous to insist that substantially all segments of the industry be present before the Court will pass upon this issue.

(*en banc*) (Friendly, J.); *Erlanger Mills, Inc. v. Cohoes Fibre Mills, Inc.*, 239 F.2d 502, 507 (4th Cir. 1956) (Sobeloff, J.).

It must be conceded that in all the cases of this Court above cited, the cause of action was understood to have "arisen" outside the state, under the prevailing jurisprudence of the time. But this point should not be controlling. Assume that in the most local kind of action against General Motors (*e.g.*, the crash of a defective car), a state court should order to the state, for the duration of a lengthy trial, all the officers of General Motors, all of its employees on a managerial level, and all of its engineers—with instructions to bring all their original books and records with them. Surely, the question of whether there has been an undue interference with interstate commerce does not turn on the talismanic point of whether or not the cause of action "arose" within the state.

With deference, petitioner submits that in some—or all—of the cases cited above, where the Court found the Commerce Clause offended solely by virtue of a requirement to litigate, the burdens on interstate commerce were minuscule, compared with the burdens created by the judgment below.

And if there is any question concerning the current vitality of the Commerce Clause precedents, the present case furnishes a suitable occasion for revisiting that issue.

H. *The Sindell problem in other jurisdictions.* Added urgency in reviewing *Sindell* comes from the fact that decisions are beginning to emerge in other jurisdictions that pose essentially the same problems.

A New Jersey court has decided a DES case in a manner basically similar to *Sindell.*[13]

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[13]*Ferrigno v. Eli Lilly and Company, et al.*, No. L-41104-75, L-15621-76, N.J. Super. Ct., Hudson Co., July 2, 1980.

A Michigan court has decided a DES case in a manner that likewise points in the direction of industry-wide litigation and industry-wide recoveries. The Michigan case does not rest on the market-share theory of *Sindell*, but has similar implications in terms of the burdensomeness of litigation, and even more serious implications in terms of the substantive unfairness of the result.[14]

Although the approach taken in these cases represents a minority viewpoint.[15] The pressing problem posed by *Sindell* itself is magnified by these developments in other jurisdictions.

II.

Assuming That Petitioner Can Be Compelled to Defend in the California Courts, the Sindell Rule Is Unconstitutional Because of Its Arbitrariness and Unfairness in Distributing Losses Among Members of the Industry Inter Se.

A. *The present reviewability of this aspect of the judgment*. Petitioner has shown that the judgment below is prop-

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[14] *Abel v. Eli Lilly Company, et al.*, ... Mich. App. ....., 289 N.W.2d 20 (1979), *appeal pending*. So far as is here pertinent, the holding in *Abel* rests on the theory of "alternative liability." Under this theory, the burden of proving noncausation is shifted to the defendants, who become liable if unable to meet the burden. The liability is joint and several, subject to apportionment through rules of contribution and comparative fault, to the extent that the jurisdiction has such rules. Inevitably, the "alternative liability" basis of recovery would make for participation of virtually all the members of the industry in the defense (the Michigan court in effect invited impleader of the entire industry, 289 N.W.2d at 26), with all the burdensomeness attendant upon litigation under the *Sindell* rule. The substantive consequences are likely to be especially severe, since the smaller producers would tend to fare worse than under the "market share" principle of *Sindell*.

It may also be noted that, in a case now on appeal, a New York jury granted a recovery despite the plaintiff's inability to identify a particular defendant as the DES source. *Bichler v. Eli Lilly and Company* (Sup. Ct., N.Y. 1979).

[15] The plaintiff was held bound to identify the DES maker in *Gray v. United States*, 445 F.Supp. 337 (S.D. Tex. 1978). All the other like cases are unreported.

erly before this Court in view of the claim that petitioner cannot constitutionally be compelled to defend in the state courts. This being so, the Court has jurisdiction to consider other denials of federal right flowing from that judgment. *Cf. Flournoy v. Wiener*, 321 U.S. 253, 263 (1944); *Prudential Insurance Co. v. Cheek*, 259 U.S. 530, 547 (1922).

In any event, insofar as petitioner challenges the judgment in its establishment of a rule of substantive liability, the judgment in this regard too is final within the meaning of 28 U.S.C. § 1257, if it can be shown that failure to render a prompt decision on this clearly separable and determinative federal issue "might seriously erode federal policy." *Cox Broadcasting Corp. v. Cohn*, 420 U.S. 469, 483 (1975). That there would be such erosion is, petitioner submits, amply revealed by the discussion that follows. It will be demonstrated that the judgment below, considered in its substantive aspect alone, casts a heavy shadow over much of American industry. Further, to defer consideration of the substantive aspect until consummation of at least one round of the extraordinarily burdensome litigation portended by Sindell (whether or not such burdensomeness is itself unconstitutional), would also make for the erosion of the constitutional policies that condemn *Sindell* in its substantive aspect.

B. *The arbitrary and unfair character of the rule of liability.* As previously noted, the California court thought it fair to assume that the maker of a harmful fungible product with, say, 10 percent of the relevant market, is causing 10 percent of the actual harm in that market. Consequently, in the view of the court, holding the defendants jointly liable for the damages of each individual plaintiff, and dividing the judgment among themselves in amounts proportionate to each defendant's share of the market would result, ideally, in imposing liability on each defendant "approximately equivalent to the damages [it actually] caused" (App. 27).

The court saw the possibility of "minor discrepancy" between the totality of liability imposed on a firm and the totality of the damages it had actually caused in the market area, but dismissed this as "inevitable." (App. 28). Petitioner submits that the "inevitable" discrepancies will not be "minor" but major, to the point of constitutional infirmity.

But, putting aside the devastating transactions costs flowing from the resort to ordinary judicial processes, the court's notion of a judicial equivalent departs from the above model in a crucial respect. Under *Sindell,* a pharmaceutical firm is liable for 100 percent of the plaintiff's damages if identified as the actual supplier of the DES. Also, since proof that a firm was not the actual supplier is a defense, there may be situations in which full liability would be fastened upon relatively small groups of suppliers. For example, if it is determined that the DES was ingested in the form of a green pill, full liability would fall upon the defendants whose DES was marketed as a green pill. Or, if the DES in question is traced to a particular wholesaler who carried the DES of six producers, and further identification of the actual source is not possible, the six producers would carry the full burden of the plaintiff's damages.

Thus, where no identification whatever can be made, *all* firms would be liable in amounts corresponding to the harm that, in theory, they actually caused. And *some* firms would be subject to heavy incremental liability, where identification is possible.

None of this is fanciful. Eli Lilly and Company is now a defendant in a total of 148 suits, in 41 of which it is alleged to have been the maker of the DES ingested by the plaintiff's mother. In a case now pending in Michigan on appeal, 70 out of a total of 182 plaintiffs have advanced claims that a particular maker was the source of the DES

ingested by their mothers.[16] If, after *Sindell*, plaintiffs will be less inclined to identify the DES source, the assembled defendants may be counted upon to pursue this line of inquiry vigorously.[17]

In short, the California plan would produce a severe imbalance in the distribution of losses among members of the industry, with multiple burdens falling on individual firms in a random manner. The Court's stated assumption that its plan would achieve approximate equivalence between the harm caused by a particular firm and the damages assessed against that firm is patently unfounded.

C. *The bases for constitutional invalidity*. The California plan is no less constitutionally vulnerable because embodied in judicial legislation than if it were embodied in a statute. *Cf. New York Times v. Sullivan*, 376 U.S. 254 (1964).

As has been seen, *Sindell* rests on the presumption—an irrebuttable presumption at that—to the effect that, in the absence of identification, holding the defendant liable in every case in an amount proportionate to its market share will approximate in dollar amount the harm actually caused by the defendant. For the reasons advanced, this presump-

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[16]*Abel v. Eli Lilly and Company, et al., supra* note 14, 284 N.W. 2d at 23.

[17]Incidentally, distortions of this kind would not be eliminated if the *Sindell* rule were modified to provide that the liability of a defendant should *never* exceed its market share, even if the defendant is identified as the DES source.

This is because the relevant market (which *Sindell* left undefined) is likely to be a regional market—since to impose liability on the basis of a firm's share of the national market would arguably be beyond the competence of a state, and arguably unfair to firms having an insignificant share of the regional market. But if regional markets were used, there would inevitably be overlapping from one case to another, with serious distortions flowing from that factor alone. These distortions become even more pronounced when account is taken additionally of the factor of incremental liability discussed in the text.

tion is irrational, and hence in contravention of the Due Process Clause of the Fourteenth Amendment. *E.g., Tot v. United States*, 319 U.S. 463, 467-68 (1943).[18] In any event, *Sindell* is invalid under the Equal Protection Clause for "[failing] even the rationality test," see *New Orleans v. Dukes*, 427 U.S. 297, 304 (1976); and for the same reason it is invalid under the Due Process Clause as well, see *Vlandis v. Kline*, 412 U.S. 441, 450 (1973).

Moreover, *Sindell* will burden interstate commerce, in contravention of the Commerce Clause, far more than the Wisconsin trucking regulations invalidated in *Raymond Motor Transportation, Inc. v. Rice*, 434 U.S. 429 (1978). The *Sindell* rule is not one with an "only incidental" effect on interstate commerce. See *Pike v. Bruce Church, Inc.*, 397 U.S. 137, 142 (1970).

Sindell has obvious implications extending beyond pharmaceutical products; it has cast a heavy pall over much of American industry. The substantive aspect of *Sindell*, like its procedural aspect, warrants prompt consideration by this Court.

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[18]Another unconstitutional presumption is implicit in the *Sindell* rationale. This is suggested by the situation of the defendant whose share of the relevant market is extremely small. Such a defendant (like any other) can escape liability by showing that its own DES was not ingested by plaintiff's mother. But, in attempting to make this showing, such a defendant would apparently be precluded from asking the jury to consider the pertinence of its insignificant market share, since to allow evidence of market share on the issue of causation-in-fact would undermine the court's determination to found liability entirely on market share. Thus the court has sanctioned the defense of non-causation, provable by a possibly inferior type of evidence (*e.g.*, disputed recollections), but not provable, it seems, by evidence that any rational fact-finder might find vastly more persuasive. *Cf. Vlandis v. Kline*, 412 U.S. 441 (1973).

Conclusion.

For the foregoing reasons, it is respectfully submitted that this petition for a writ of certiorari should be granted.

Respectfully submitted,

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APPENDIX A.

Opinion of the California Supreme Court.

In the Supreme Court of the State of California, Judith Sindell, Plaintiff and Appellant, v. Abbott Laboratories et al., Defendants and Respondents. Maureen Rogers, Plaintiff and Appellant, v. Rexall Drug Company et al., Defendants and Respondents. L.A. 31063.

Filed: March 20, 1980.

This case involves a complex problem both timely and significant: may a plaintiff, injured as the result of a drug administered to her mother during pregnancy, who knows the type of drug involved but cannot identify the manufacturer of the precise product, hold liable for her injuries a maker of a drug produced from an identical formula?

Plaintiff Judith Sindell brought an action against eleven drug companies and Does 1 through 100, on behalf of herself and other women similarly situated. The complaint alleges as follows:

Between 1941 and 1971, defendants were engaged in the business of manufacturing, promoting, and marketing diethylstilbesterol (DES), a drug which is a synthetic compound of the female hormone estrogen. The drug was administered to plaintiff's mother and the mothers of the class she represents,[1] for the purpose of preventing miscarriage. In 1947, the Food and Drug Administration authorized the marketing of DES as a miscarriage

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[1]The plaintiff class alleged consists of "girls and women who are residents of California and who have been exposed to DES before birth and who may or may not know that fact or the dangers" to which they were exposed. Defendants are also sued as representatives of a class of drug manufacturers which sold DES after 1941.

preventative, but only on an experimental basis, with a requirement that the drug contain a warning label to that effect.

DES may cause cancerous vaginal and cervical growths in the daughters exposed to it before birth, because their mothers took the drug during pregnancy. The form of cancer from which these daughters suffer is known as adenocarcinoma, and it manifests itself after a minimum latent period of 10 or 12 years. It is a fast-spreading and deadly disease, and radical surgery is required to prevent it from spreading. DES also causes adenosis, precancerous vaginal and cervical growths which may spread to other areas of the body. The treatment for adenosis is cauterization, surgery, or cryosurgery. Women who suffer from this condition must be monitored by biopsy or colposcopic examination twice a year, a painful and expensive procedure. Thousands of women whose mothers received DES during pregnancy are unaware of the effects of the drug.

In 1971, the Food and Drug Administration ordered defendants to cease marketing and promoting DES for the purpose of preventing miscarriages, and to warn physicians and the public that the drug should not be used by pregnant women because of the danger to their unborn children.

During the period defendants marketed DES, they knew or should have known that it was a carcinogenic substance, that there was a grave danger after varying periods of latency it would cause cancerous and precancerous growths in the daughters of the mothers who took it, and that it was ineffective to prevent miscarriage. Nevertheless, defendants continued to advertise and market the drug as a miscarriage preventative. They failed to test DES for efficacy and safety; the tests performed by others, upon which they relied, indicated that it was not safe or effective. In violation of the authorization of the Food and Drug Administration, de-

fendants marketed DES on an unlimited basis rather than as an experimental drug, and they failed to warn of its potential danger.[2]

Because of defendants' advertised assurances that DES was safe and effective to prevent miscarriage, plaintiff was exposed to the drug prior to her birth. She became aware of the danger from such exposure within one year of the time she filed her complaint. As a result of the DES ingested by her mother, plaintiff developed a malignant bladder tumor which was removed by surgery. She suffers from adenosis and must constantly be monitored by biopsy or colposcopy to insure early warning of further malignancy.

The first cause of action alleges that defendants were jointly and individually negligent in that they manufactured, marketed and promoted DES as a safe and efficacious drug to prevent miscarriage, without adequate testing or warning, and without monitoring or reporting its effects.

A separate cause of action alleges that defendants are jointly liable regardless of which particular brand of DES was ingested by plaintiff's mother because defendants collaborated in marketing, promoting and testing the drug, relied upon each other's tests, and adhered to an industry-wide safety standard. DES was produced from a common and mutually agreed upon formula as a fungible drug interchangeable with other brands of the same product; defendants knew or should have known that it was customary for doctors to prescribe the drug by its generic rather than its brand name and that pharmacists filled prescriptions from whatever brand of the drug happened to be in stock.

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[2]It is alleged also that defendants failed to determine if there was any means to avoid or treat the effects of DES upon the daughters of women exposed to it during pregnancy, and failed to monitor the carcinogenic effects of the drug.

Other causes of action are based upon theories of strict liability, violation of express and implied warranties, false and fraudulent representations, misbranding of drugs in violation of federal law, conspiracy and "lack of consent."

Each cause of action alleges that defendants are jointly liable because they acted in concert, on the basis of express and implied agreements, and in reliance upon and ratification and exploitation of each other's testing and marketing methods.

Plaintiff seeks compensatory damages of $1 million and punitive damages of $10 million for herself. For the members of her class, she prays for equitable relief in the form of an order that defendants warn physicians and others of the danger of DES and the necessity of performing certain tests to determine the presence of disease caused by the drug, and that they establish free clinics in California to perform such tests.

Defendants demurred to the complaint. While the complaint did not expressly allege that plaintiff could not identify the manufacturer of the precise drug ingested by her mother, she stated in her points and authorities in opposition to the demurrers filed by some of the defendants that she was unable to make the identification, and the trial court sustained the demurrers of these defendants without leave to amend on the ground that plaintiff did not and stated she could not identify which defendant had manufactured the drug responsible for her injuries. Thereupon, the court dis-

missed the action.[3] This appeal involves only five of ten defendants named in the complaint.[4]

Plaintiff Maureen Rogers filed a complaint containing allegations generally similar to those made by Sindell. She seeks compensatory and punitive damages on her own behalf, and on behalf of a class described in substantially the same terms as in Sindell's complaint, as well as equitable relief comparable to that sought by Sindell. The trial court sustained demurrers of E.R. Squibb & Sons, The Upjohn

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[3]There are minor variations in the procedures employed as to the various defendants. Thus, for example, Eli Lilly and Company filed a motion for summary judgment, or alternatively judgment on the pleadings, rather than a demurrer; the court treated the motion as a demurrer.

The demurrer of Abbott Laboratories, the first defendant to file a demurrer and the first to secure a dismissal, was sustained with leave to amend on the ground that plaintiff had failed to allege that a product manufactured by Abbott had caused her injuries (as opposed to the reason given by the trial court for sustaining the demurrers of the other defendants that plaintiff expressly stated that she could not identify a particular manufacturer). Upon plaintiff's failure to amend the complaint, the action was dismissed as to Abbott. A few days after the dismissal, plaintiff stated in a brief in opposition to the demurrers filed by defendants other than Abbott that she could not make the identification.

Abbott asserts that as to it the issue we consider on the appeal is not properly raised because plaintiff's statement that she could not identify the manufacturer was not made until after the action had been dismissed as to Abbott. This contention is without merit. Plaintiff's failure to amend her complaint after Abbott's demurrer was sustained with leave to amend was based upon her inability to identify a specific manufacturer. Clearly, Abbott interpreted the complaint in this fashion, for it moved for dismissal on the ground that the complaint alleges that plaintiff "does not know the identity of the drug . . . ingested" by her mother. Thus, Abbott may not now claim that the complaint is insufficient to raise the issue involved in this appeal.

The trial court did not determine other issues raised by the complaint, such as whether the case was properly brought as a class action.

[4]Abbott Laboratories, Eli Lilly and Company, E.R. Squibb and Sons, The Upjohn Company, and Rexall Drug Company are respondents. The action was dismissed or the appeal abandoned on various grounds as to other defendants named in the complaint; e.g., one defendant demonstrated it had not manufactured DES during the period plaintiff's mother took the drug.

Company, and Rexall Drug Company.[5] Subsequent to the dismissal of her action against these defendants, Rogers amended the complaint to allege that Eli Lilly and Company, one of the defendants named in her complaint, had manufactured the drug used by her mother. Although Sindell's action and the present case have been consolidated on appeal, much of the discussion which follows will apply to Rogers only if she does not succeed in establishing that Eli Lilly and Company manufactured the DES taken by her mother. "Plaintiff" as used in this opinion refers to Sindell, and we discuss only the allegations of Sindell's complaint.

This case is but one of a number filed throughout the country seeking to hold drug manufacturers liable for injuries allegedly resulting from DES prescribed to the plaintiffs' mothers since 1947.[6] According to a note in the Fordham Law Review, estimates of the number of women who took the drug during pregnancy ranged from 1½ million to 3 million. Hundreds, perhaps thousands, of the daughters of these women suffer from adenocarcinoma, and the incidence of vaginal adenosis among them is 30 to 90 percent. (Comment, *DES and a Proposed Theory of Enterprise Liability* (1978) 46 Fordham L.Rev. 963, 964-967 [hereafter Fordham Comment].) Most of the cases are still pending. With two exceptions,[7] those that have been decided resulted

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[5]While the trial court did not specify the ground upon which the demurrers were sustained, the points and authorities filed by the parties emphasized the failure of Rogers to identify a particular manufacturer as the source of her injuries, and we may assume for the purpose of this appeal that this was the basis of the court's order.

[6]DES was marketed under many different trade names.

[7]In a recent New York case a jury found in the plaintiff's favor in spite of her inability to identify a specific manufacturer of DES. An appeal is pending. (Bichler v. Eli Lilly and Co. (Sup.Ct.N.Y. 1979).) A Michigan appellate court recently held that plaintiffs had stated a cause of action against several manufactuers of DES even though identification could not be made. (Abel v. Eli Lilly and Co. (decided Dec. 5, 1979) Docket No. 60497.) That decision is on appeal to the Supreme Court of Michigan.

in judgments in favor of the drug company defendants because of the failure of the plaintiffs to identify the manufacturer of the DES prescribed to their mothers.[8] The same result was reached in a recent California case. (*McCreery v. Eli Lilly & Co.* (1978) 87 Cal.App.3d 77, 82-84.) The present action is another attempt to overcome this obstacle to recovery.

We begin with the proposition that, as a general rule, the imposition of liability depends upon a showing by the plaintiff that his or her injuries were caused by the act of the defendant or by an instrumentality under the defendant's control. The rule applies whether the injury resulted from an accidental event (e.g., Shunk v. Bosworth (6th Cir. 1964) 334 F.2d 309) or from the use of a defective product. (E.g., Wetzel v. Eaton Corporation (D.Minn. 1973) 62 F.R.D. 22, 29-30; Garcia v. Joseph Vince Co. (1978) 84 Cal.App.3d 868, 873-875; and see annot. collection of cases in 51 A.L.R.3d 1344, 1351; 1 Hursh and Bailey, American Law of Products Liability 2d (1974) p. 125.)

There are, however, exceptions to this rule. Plaintiff's complaint suggests several bases upon which defendants may be held liable for her injuries even though she cannot demonstrate the name of the manufacturer which produced the DES actually taken by her mother. The first of these theories, classically illustrated by Summers v. Tice (1948) 33 Cal.2d 80, places the burden of proof of causation upon tortious defendants in certain circumstances. The second

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[8]E.g., Gray v. United States (S.D. Texas 1978) 445 F.Supp. 337. In their briefs, defendants refer to a number of other cases in which trial courts have dismissed actions in DES cases on the ground stated above.

basis of liability emerging from the complaint is that defendants acted in concert to cause injury to plaintiff. There is a third and novel approach to the problem, sometimes called the theory of "enterprise liability," but which we prefer to designate by the more accurate term of "industry-wide" liability,[9] which might obviate the necessity for identifying the manufacturer of the injury-causing drug. We shall conclude that these doctrines, as previously interpreted, may not be applied to hold defendants liable under the allegations of this complaint. However, we shall propose and adopt a fourth basis for permitting the action to be tried, grounded upon an extension of the *Summers* doctrine.

I

Plaintiff places primary reliance upon cases which hold that if a party cannot identify which of two or more defendants caused an injury, the burden of proof may shift to the defendants to show that they were not responsible for the harm. This principle is sometimes referred to as the "alternative liability" theory.

The celebrated case of Summers v. Tice, supra, 33 Cal.2d 80, a unanimous opinion of this court, best exemplifies the rule. In *Summers*, the plaintiff was injured when two hunters negligently shot in his direction. It could not be determined which of them had fired the shot which actually caused the injury to the plaintiff's eye, but both defendants were nevertheless held jointly and severally liable for the whole of the damages. We reasoned that both were wrongdoers, both were negligent toward the plaintiff, and that it would be unfair to require plaintiff to isolate the defendant respon-

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[9]The term "enterprise liability" is sometimes used broadly to mean that losses caused by an enterprise should be borne by it. (Klemme, Enterprise Liability (1976) 47 Colo. L.Rev. 153, 158.)

sible, because if the one pointed out were to escape liability, the other might also, and the plaintiff-victim would be shorn of any remedy. In these circumstances, we held, the burden of proof shifted to the defendants, "each to absolve himself if he can." (*Id.*, p. 86.) We stated that under these or similar circumstances a defendant is ordinarily in a "far better position" to offer evidence to determine whether he or another defendant caused the injury.

In *Summers*, we relied upon Ybarra v. Spangard (1944) 25 Cal.2d 486. There, the plaintiff was injured while he was unconscious during the course of surgery. He sought damages against several doctors and a nurse who attended him while he was unconscious. We held that it would be unreasonable to require him to identify the particular defendant who had performed the alleged negligent act because he was unconscious at the time of the injury and the defendants exercised control over the instrumentalities which caused the harm. Therefore, under the doctrine of res ipsa loquitur, an inference of negligence arose that defendants were required to meet by explaining their conduct.[10]

The rule developed in *Summers* has been embodied in the Restatement of Torts. (Rest.2d Torts, § 433B, subsec.

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[10]Other cases cited by plaintiff for the proposition stated in *Summers* are only peripherally relevant. For example, in Ray v. Alad Corporation (1977) 19 Cal.3d 22, the plaintiff brought an action in strict liability for personal injuries sustained when he fell from a defective ladder manufactured by the defendant's predecessor corporation. We held that, although under the general rule governing corporate succession the defendant could not be held responsible, nevertheless a "special departure" from that rule was justified in the particular circumstances. The defendant had succeeded to the good will of the manufacturer of the ladder, and it could obtain insurance against the risk of liability, whereas the plaintiff would be left without redress if he could not hold the defendant liable. The question whether one corporation should, for policy reasons, be answerable for the products manufactured by its predecessor is a different issue than that we describe above.

(3).)[11] Indeed, the *Summers* facts are used as an illustration (p. 447).

Defendants assert that these principles are inapplicable here. First, they insist that a predicate to shifting the burden of proof under *Summers-Ybarra* is that the defendants must have greater access to information regarding the cause of the injuries than the plaintiff, whereas in the present case the reverse appears.

Plaintiff does not claim that defendants are in a better position than she to identify the manufacturer of the drug taken by her mother or, indeed, that they have the ability to do so at all, but argues, rather that *Summers* does not impose such a requirement as a condition to the shifting of the burden of proof. In this respect we believe plaintiff is correct.

In *Summers*, the circumstances of the accident themselves precluded an explanation of its cause. To be sure, *Summers* states that defendants are "[o]rdinarily . . . in a far better position to offer evidence to determine which one caused the injury" than a plaintiff (33 Cal.2d 80, at p. 86), but the decision does not determine that this "ordinary" situation was present. Neither the facts nor the language of the opinion indicate that the two defendants, simultaneously shooting in the same direction, were in a better position than the

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[11]Section 433B, subsection (3) of the Restatement provides: "Where the conduct of two or more actors is tortious, and it is proved that harm has been caused to the plaintiff by only one of them, but there is uncertainty as to which one has caused it, the burden is upon each such actor to prove that he has not caused the harm." The reason underlying the rule is "the injustice of permitting proved wrongdoers, who among them have inflicted an injury upon the entirely innocent plaintiff, to escape liability merely because the nature of their conduct and the resulting harm has made it difficult or impossible to prove which of them has caused the harm." (Rest.2d Torts, § 433B, com. f, p. 446.)

plaintiff to ascertain whose shot caused the injury. As the opinion acknowledges, it was impossible for the trial court to determine whether the shot which entered the plaintiff's eye came from the gun of one defendant or the other. Nevertheless, burden of proof was shifted to the defendants.

Here, as in *Summers*, the circumstances of the injury appear to render identification of the manufacturer of the drug ingested by plaintiff's mother impossible by either plaintiff or defendants, and it cannot reasonably be said that one is in a better position than the other to make the identification. Because many years elapsed between the time the drug was taken and the manifestation of plaintiff's injuries she, and many other daughters of mothers who took DES, are unable to make such identification.[12] Certainly there can be no implication that plaintiff is at fault in failing to do so — the event occurred while plaintiff was *in utero*, a generation ago.[13]

On the other hand, it cannot be said with assurance that defendants have the means to make the identification. In this connection, they point out that drug manufacturers ordinarily have no direct contact with the patients who take a drug prescribed by their doctors. Defendants sell to whole-

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[12]The trial court was not required to determine whether plaintiff had made sufficient efforts to establish identification since it concluded that her failure to do so was fatal to her claim. The court accepted at face value plaintiff's assertion that she could not make the identification, and for purposes of this appeal we make the same assumption.

[13]Defendants maintain that plaintiff is in a better position than they are to identify the manufacturer because her mother might recall the name of the prescribing physician or the hospital or pharmacy where the drug originated, and might know the brand and strength of dosage, the appearance of the medication, or other details from which the manufacturer might be identified, whereas they possess none of this information. As we point out in footnote 12, we assume for purposes of this appeal that plaintiff cannot point to any particular manufacturer as the producer of the DES taken by her mother.

salers, who in turn supply the product to physicians and pharmacies. Manufacturers do not maintain records of the persons who take the drugs they produce, and the selection of the medication is made by the physician rather than the manufacturer. Nor do we conclude that the absence of evidence on this subject is due to the fault of defendants. While it is alleged that they produced a defective product with delayed effects and without adequate warnings, the difficulty or impossibility of identification results primarily from the passage of time rather than from their allegedly negligent acts of failing to provide adequate warnings. Thus Haft v. Lone Palm Hotel (1970) 3 Cal.3d 756, upon which plaintiff relies, is distinguishable.[14]

It is important to observe, however, that while defendants do not have means superior to plaintiff to identify the maker of the precise drug taken by her mother, they may in some instances be able to prove that they did not manufacture the injury-causing substance. In the present case, for example, one of the original defendants was dismissed from the action

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[14]In *Haft*, a father and his young son drowned in defendants' swimming pool. There were no witnesses to the accident. Defendants were negligent in failing to provide a lifeguard, as required by law. We held that the absence of evidence of causation was a direct and foreseeable result of the defendants' negligence, and that, therefore, the burden of proof on the issue of causation was upon defendants. Plaintiff attempts to bring herself within this holding. She asserts that defendants' failure to discover or warn of the dangers of DES and to label the drug as experimental caused her mother to fail to keep records or remember the brand name of the drug prescribed to her "since she was unaware of any reason to do so for a period of 10 to 20 years." There is no proper analogy to *Haft* here. While in *Haft* the presence of a lifeguard on the scene would have provided a witness to the accident and probably prevented it, plaintiff asks us to speculate that if the DES taken by her mother had been labelled as an experimental drug, she would have recalled or recorded the name of the manufacturer and passed this information on to her daughter. It cannot be said here that the absence of evidence of causation was a "direct and foreseeable result" of defendants' failure to provide a warning label.

upon proof that it did not manufacture DES until after plaintiff was born.

Thus we conclude that the fact defendants do not have greater access to information which might establish the identity of the manufacturer of the DES which injured plaintiff does not per se prevent application of the *Summers* rule.

Nevertheless, plaintiff may not prevail in her claim that the *Summers* rationale should be employed to fix the whole liability for her injuries upon defendants, at least as those principles have previously been applied.[15] There is an important difference between the situation involved in *Summers* and the present case. There, all the parties who were or could have been responsible for the harm to the plaintiff were joined as defendants. Here, by contrast, there are approximately 200 drug companies which made DES, any of which might have manufactured the injury-producing drug.[16]

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[15]Plaintiff relies upon three older cases for the proposition that the burden of proof may be shifted to defendants to explain the cause of an accident even if less than all of them are before the court. (Benson v. Ross (Mich. 1906) 106 N.W. 1120; Moore v. Foster (Miss. 1938) 180 So. 73; Oliver v. Miles (Miss. 1927) 110 So. 666.) These cases do not relate to the shifting of the burden of proof; rather, they imposed liability upon one of two or more joint tortfeasors on the ground that they acted in concert in committing a negligent act. This theory of concerted action as a basis for defendants' liability will be discussed *infra*. In *Summers*, we stated that these cases were "straining" the concept of concerted action and that the "more reasonable" basis for holding defendants jointly liable when more than one of them had committed a tort and plaintiff could not establish the identity of the party who had caused the damage was the danger that otherwise two negligent parties might be exonerated. (*Summers*, 33 Cal.2d 80, at pp. 84-85.)

[16]According to the Restatement, the burden of proof shifts to the defendants only if the plaintiff can demonstrate that all defendants acted tortiously and that the harm resulted from the conduct of one of them. (Rest.2d Torts, § 433B, com. g, p. 446.) It goes on to state that the rule thus far has been applied only where all the actors involved are joined as defendants and where the conduct of all is simultaneous in time, but cases might arise in which some modification of the rule would be necessary if one of the actors is or cannot be joined, or because of the effects of lapse of time, or other circumstances. (*Id.*, com. h, p. 446.)

Defendants maintain that, while in *Summers* there was a 50 percent chance that one of the two defendants was responsible for the plaintiff's injuries, here since any one of 200 companies which manufactured DES might have made the product which harmed plaintiff, there is no rational basis upon which to infer that any defendant in this action caused plaintiff's injuries, nor even a reasonable possibility that they were responsible.[17]

These arguments are persuasive if we measure the chance that any one of the defendants supplied the injury-causing drug by the number of possible tortfeasors. In such a context, the possibility that any of the five defendants supplied the DES to plaintiff's mother is so remote that it would be unfair to require each defendant to exonerate itself. There may be a substantial likelihood that none of the five defendants joined in the action made the DES which caused the injury, and that the offending producer not named would escape liability altogether. While we propose, *infra*, an adaptation of the rule in *Summers* which will substantially overcome these difficulties, defendants appear to be correct that the rule, as previously applied, cannot relieve plaintiff

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[17]Defendants claim further that the effect of shifting the burden of proof to them to demonstrate that they did not manufacture the DES which caused the injury would create a rebuttable presumption that one of them made the drug taken by plaintiff's mother, and that this presumption would deny them due process because there is no rational basis for the inference.

of the burden of proving the identity of the manufacturer which made the drug causing her injuries.[18]

II

The second principle upon which plaintiff relies is the so-called "concert of action" theory. Preliminarily, we briefly describe the procedure a drug manufacturer must follow before placing a drug on the market. Under federal law as it read prior to 1962, a new drug was defined as one "not generally recognized as . . . safe." (§ 102, 76 Stat. 781 (Oct. 10, 1962).) Such a substance could be marketed only if a new drug application had been filed with the Food and Drug Administration and had become "effective."[19] If the agency determined that a product was no longer a "new drug," i.e., that it was "generally recognized as . . . safe," (21 U.S.C.A. § 321, subd. (p)(1)) it could be manufactured by any drug company without submitting an application to the agency. Acording to defendants, 123 new drug appli-

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[18]Garcia v. Joseph Vince Co., supra, 84 Cal.App.3d 868, relied upon by defendants, presents a distinguishable factual situation. The plaintiff in *Garcia* was injured by a defective saber. He was unable to identify which of two manufacturers had produced the weapon because it was commingled with other sabers after the accident. In a suit against both manufacturers, the court refused to apply the *Summers* rationale on the ground that the plaintiff had not shown that either defendant had violated a duty to him. Thus in *Garcia*, only one of the two defendants was alleged to have manufactured a defective product, and the plaintiff's inability to identify which of the two was negligent resulted in a judgment for both defendants. (See also Wetzel v. Eaton, supra, 62 F.R.D. 22.) Here, by contrast, the DES manufactured by all defendants is alleged to be defective, but plaintiff is unable to demonstrate which of the defendants supplied the precise DES which caused her injuries.

[19]A new drug application became "effective" automatically if the Secretary of Health, Education and Welfare failed within a certain period of time to disapprove the application. If the agency had insufficient information to decide whether the drug was safe or had information that it was unsafe, the application was denied. (§ 505,52 Stat. 1052 (June 25, 1938).) Since 1962, affirmative approval of an application has been required before a new drug may be marketed. (21 U.S.C.A. § 355, subd. (c).)

cations for DES had been approved by 1952, and in that year DES was declared not to be a "new drug," thus allowing any manufacturer to produce it without prior testing and without submitting a new drug application to the Food and Drug Administration.

With this background we consider whether the complaint states a claim based upon "concert of action" among defendants. The elements of this doctrine are prescribed in section 876 of the Restatement of Torts. The section provides, "For harm resulting to a third person from the tortious conduct of another, one is subject to liability if he (a) does a tortious act in concert with the other or pursuant to a common design with him, or (b) knows that the other's conduct constitutes a breach of duty and gives substantial assistance or encouragement to the other so to conduct himself, or (c) gives substantial assistance to the other in accomplishing a tortious result and his own conduct, separately considered, constitutes a breach of duty to the third person." With respect to this doctrine, Prosser states that "those who, in pursuance of a common plan or design to commit a tortious act, actively take part in it, or further it by cooperation or request, or who lend aid or encouragement to the wrongdoer, or ratify and adopt his acts done for their benefit, are equally liable with him. [¶] Express agreement is not necessary, and all that is required is that there be a tacit understanding. . . ." (Prosser, Law of Torts (4th ed. 1971), sec. 46, p. 292.)

Plaintiff contends that her complaint states a cause of action under these principles. She alleges that defendants' wrongful conduct "is the result of planned and concerted action, express and implied agreements, collaboration in, reliance upon, acquiescence in and ratification, exploitation and adoption of each other's testing, marketing methods, lack of warnings . . . and other acts or omissions . . ." and

that "acting individually and in concert, [defendants] promoted, approved, authorized, acquiesced in, and reaped profits from sales" of DES. These allegations, plaintiff claims, state a "tacit understanding" among defendants to commit a tortious act against her.

In our view, this litany of charges is insufficient to allege a cause of action under the rules stated above. The gravamen of the charge of concert is that defendants failed to adequately test the drug or to give sufficient warning of its dangers and that they relied upon the tests performed by one another and took advantage of each others' promotional and marketing techniques. These allegations do not amount to a charge that there was a tacit understanding or a common plan among defendants to fail to conduct adequate tests or give sufficient warnings, and that they substantially aided and encouraged one another in these omissions.

The complaint charges also that defendants produced DES from a "common and mutually agreed upon formula," allowing pharmacists to treat the drug as a "fungible commodity" and to fill prescriptions from whatever brand of DES they had on hand at the time. It is difficult to understand how these allegations can form the basis of a cause of action for wrongful conduct by defendants, acting in concert. The formula for DES is a scientific constant. It is set forth in the United States Pharmacopoeia, and any manufacturer producing that drug must, with exceptions not relevant here, utilize the formula set forth in that compendium. (21 U.S.C.A. § 351, subd. (b).)

What the complaint appears to charge is defendants' parallel or imitative conduct in that they relied upon each others' testing and promotion methods. But such conduct describes a common practice in industry: a producer avails himself of the experience and methods of others making the same or similar products. Application of the concept of

concert of action to this situation would expand the doctrine far beyond its intended scope and would render virtually any manufacturer liable for the defective products of an entire industry, even if it could be demonstrated that the product which caused the injury was not made by the defendant.

None of the cases cited by plaintiff supports a conclusion that defendants may be held liable for concerted tortious acts. They involve conduct by a small number of individuals whose actions resulted in a tort against a single plaintiff, usually over a short span of time, and the defendant held liable was either a direct participant in the acts which caused damage,[20] or encouraged and assisted the person who directly caused the injuries by participating in a joint activity.[21]

Orser v. George (1967) 252 Cal.App.2d 660, upon which plaintiff primarily relies, is also distinguishable. There, three hunters negligently shot at a mudhen in decedent's direction. Two of them shot alternately with the gun which released the bullet resulting in the fatal wound, and the third, using a different gun, fired alternately at the same target, shooting in the same line of fire, perhaps acting tortiously. It was held that there was a possibility the third hunter knew the conduct of the others was tortious toward

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[20]Weinberg Co. v. Bixby (1921) 185 Cal. 87, 103, involved a husband who was held liable with his wife for wrongful diversion of flood waters although he had given his wife title to the land upon which the outlet causing the diversion was constructed. He not only owned land affected by the flood waters, but he was his wife's agent for the purpose of reopening the outlet which caused the damage. In Meyer v. Thomas (1936) 18 Cal.App.2d 299, 305-306, both defendants participated in the conversion of a note and deed of trust.

[21]In Agovino v. Kunze (1960) 181 Cal.App.2d 591, 599, a participant in a drag race was held liable for injuries to a plaintiff who collided with the car of another racer. In Loeb v. Kimmerle (1932) 215 Cal. 143, 151, a defendant who encouraged another defendant to commit an assault was held jointly liable for the plaintiff's injuries. Also see Weirum v. RKO General, Inc. (1975) 15 Cal.3d 40.

the decedent and gave them substantial assistance and encouragement, and that it was also possible his conduct, separately considered, was a breach of duty toward decedent. Thus, the granting of summary judgment was reversed as to the third hunter.

The situation in *Orser* is similar to Agovino v. Kunze, supra, 181 Cal.App.2d 591, in which liability was imposed upon a participant in a drag race, rather than to the facts alleged in the present case. There is no allegation here that each defendant knew the other defendants' conduct was tortious toward plaintiff, and that they assisted and encouraged one another to inadequately test DES and to provide inadequate warnings. Indeed, it seems dubious whether liability on the concert of action theory can be predicated upon substantial assistance and encouragement given by one alleged tortfeasor to another pursuant to a tacit understanding to fail to perform an act. Thus, there was no concert of action among defendants within the meaning of that doctrine.

III

A third theory upon which plaintiff relies is the concept of industry-wide liability, or according to the terminology of the parties, "enterprise liability." This theory was suggested in Hall v. E. I. Du Pont de Nemours & Co., Inc. (E.D.N.Y. 1972) 345 F.Supp. 353. In that case, plaintiffs were 13 children injured by the explosion of blasting caps in 12 separate incidents which occurred in 10 different states between 1955 and 1959. The defendants were six blasting cap manufacturers, comprising virtually the entire blasting cap industry in the United States, and their trade association. There were, however, a number of Canadian blasting cap manufacturers which could have supplied the caps. The gravamen of the complaint was that the practice of the industry of omitting a warning on individual blasting caps

and of failing to take other safety measures created an unreasonable risk of harm, resulting in the plaintiffs' injuries. The complaint did not identify a particular manufacturer of a cap which caused a particular injury.[22]

The court reasoned as follows: there was evidence that defendants, acting independently, had adhered to an industry-wide standard with regard to the safety features of blasting caps, that they had in effect delegated some functions of safety investigation and design, such as labelling, to their trade association, and that there was industry-wide cooperation in the manufacture and design of blasting caps. In these circumstances, the evidence supported a conclusion that all the defendants jointly controlled the risk. Thus, if plaintiffs could establish by a preponderance of the evidence that the caps were manufactured by one of the defendants,

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[22]We deliberately employ the term "suggested" to describe the effect of the *Hall* opinion because of the uncertain posture of the decision as authority. The defendants moved to dismiss the action on the ground that the plaintiffs had not stated a claim, and they also sought to sever the claims of the various plaintiffs and transfer them to the district court in the place where each accident occurred. The opinion discusses various possible bases of liability, including industry-wide liability, upon the assumption that there existed a national body of state tort law. (345 F.Supp. at p. 360.) At the conclusion of its opinion, the court called for briefs on the choice-of-law issues involved in the case. In a subsequent opinion, the same court decided, after briefs had been filed on the choice-of-law question, that the plaintiffs' claims should be severed, and it transferred each one to the federal court sitting in the district where the accident occurred. (Chance v. E. I. Du Pont de Nemours & Co., Inc. (E.D.N.Y. 1974) 371 F.Supp. 439.) Thereafter, the transferred cases resulted in judgments for defendants upon various grounds unrelated to the theory of industry-wide liability. (Lehtonen v. E. I. Du Pont de Nemours & Co., Inc. (D. Mont. 1975) 389 F.Supp. 633 [failure to amend complaint within 30 days]; Davis v. E. I. Du Pont de Nemours & Co., Inc. (W.D.N.C. 1974) 400 F.Supp. 1347 [statute of limitations]; Ball v. E. I. Du Pont de Nemours & Co., Inc. (6th Cir. 1975) 519 F.2d 715 [jury verdict in favor of defendant after plaintiff identified the manufacturer of the blasting cap which caused his injuries].) The parties have not indicated the status of the remaining cases transferred.

the burden of proof as to causation would shift to all the defendants. The court noted that this theory of liability applied to industries composed of a small number of units, and that what would be fair and reasonable with regard to an industry of five or ten producers might be manifestly unreasonable if applied to a decentralized industry composed of countless small producers.[23]

Plaintiff attempts to state a cause of action under the rationale of *Hall*. She alleges joint enterprise and collaboration among defendants in the production, marketing, promotion and testing of DES, and "concerted promulgation and adherence to industry-wide testing, safety, warning and efficacy standards" for the drug. We have concluded above that allegations that defendants relied upon one another's testing and promotion methods do not state a cause of action for concerted conduct to commit a tortious act. Under the theory of industry-wide liability, however, each manufacturer could be liable for all injuries caused by DES by virtue of adherence to an industry-wide standard of safety.

In the Fordham Comment, the industry-wide theory of liability is discussed and refined in the context of its applicability to actions alleging injuries resulting from DES. The author explains causation under that theory as follows, ". . . [T]he industrywide standard becomes itself the cause of plaintiff's injury, just as defendants' joint plan is the cause of injury in the traditional concert of action plea. Each defendant's adherence perpetuates this standard, which re-

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[23]In discussing strict liability, the *Hall* court mentioned the drug industry, stating, "In cases where manufacturers have more experience, more information, and more control over the risky properties of their products than do drug manufacturers, courts have applied a broader concept of forseeability which approaches the enterprise liability rationale." (345 F.Supp. 353 at p. 370.)

sults in the manufacture of the particular, unidentifiable injury-producing product. Therefore, each industry member has contributed to plaintiff's injury." (Fordham Comment, supra, at p. 997.)

The Comment proposes seven requirements for a cause of action based upon industry-wide liability,[24] and suggests that if a plaintiff proves these elements, the burden of proof of causation should be shifted to the defendants, who may exonerate themselves only by showing that their product could not have caused the injury.[25]

We decline to apply this theory in the present case. At least 200 manufacturers produced DES; *Hall*, which involved 6 manufacturers representing the entire blasting cap

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[24]The suggested requirements are as follows:

1. There existed an insufficient, industry-wide standard of safety as to the manufacture of the product.

2. Plaintiff is not at fault for the absence of evidence identifying the causative agent but, rather, this absence of proof is due to defendant's conduct.

3. A generically similar defective product was manufactured by all the defendants.

4. Plaintiff's injury was caused by this defect.

5. Defendants owed a duty to the class of which plaintiff was a member.

6. There is clear and convincing evidence that plaintiff's injury was caused by a product made by one of the defendants. For example, the joined defendants accounted for a high percentage of such defective products on the market at the time of plaintiff's injury.

7. All defendants were tortfeasors.

[25]The Fordham Comment takes exception to one aspect of the theory of industry-wide liability as set forth in *Hall*, i.e., the conclusion that a plaintiff is only required to show by a preponderence of the evidence that one of the defendants manufactured the product which caused her injury. The Comment suggests that a plaintiff be required to prove by clear and convincing evidence that one of the defendants before the court was responsible and that this standard of proof would require that the plaintiff join in the action the producers of 75 or 80 percent of the DES prescribed for prevention of miscarriage. It is also suggested that the damages be apportioned among the defendants according to their share of the market for DES. (Fordham Comment, supra, 999-1000.)

industry in the United States, cautioned against application of the doctrine espoused therein to a large number of producers. (345 F.Supp. at p. 378.) Moreover, in *Hall*, the conclusion that the defendants jointly controlled the risk was based upon allegations that they had delegated some functions relating to safety to a trade association. There are no such allegations here, and we have concluded above that plaintiff has failed to allege liability on a concert of action theory.

Equally important, the drug industry is closely regulated by the Food and Drug Administration, which actively controls the testing and manufacture of drugs and the method by which they are marketed, including the contents of warning labels.[26] To a considerable degree, therefore, the standards followed by drug manufacturers are suggested or compelled by the government. Adherence to those standards cannot, of course, absolve a manufacturer of liability to which it would otherwise be subject. (Stevens v. Parke, Davis & Co. (1973) 9 Cal.3d 51, 65.) But since the government plays such a pervasive role in formulating the criteria for the testing and marketing of drugs, it would be unfair to impose upon a manufacturer liability for injuries resulting from the use of a drug which it did not supply simply because it followed the standards of the industry.[27]

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[26]Federal regulations may specify the type of tests a manufacturer must perform for certain drugs (21 C.F.R. § 436.206 et seq.), the type of packaging used (§ 429.10), the warnings which appear on labels (§ 369.20), and the standards to be followed in the manufacture of a drug (§ 211.22 et seq.).

[27]Abel v. Eli Lilly and Company, the Michigan case referred to above which held that the plaintiffs had stated a cause of action against several manufacturers of DES even though they could not identify a particular manufacturer as the source of a particular injury (see fn. 7, *ante*), relied upon the theories of concerted action and alternative liability.

IV

If we were confined to the theories of *Summers* and *Hall*, we would be constrained to hold that the judgment must be sustained. Should we require that plaintiff identify the manufacturer which supplied the DES used by her mother or that all DES manufacturers be joined in the action, she would effectively be precluded from any recovery. As defendants candidly admit, there is little likelihood that all the manufacturers who made DES at the time in question are still in business or that they are subject to the jurisdiction of the California courts. There are, however, forceful arguments in favor of holding that plaintiff has a cause of action.

In our contemporary complex industrialized society, advances in science and technology create fungible goods which may harm consumers and which cannot be traced to any specific producer. The response of the courts can be either to adhere rigidly to prior doctrine, denying recovery to those injured by such products, or to fashion remedies to meet these changing needs. Just as Justice Traynor in his landmark concurring opinion in Escola v. Coca Cola Bottling Company (1944) 24 Cal.2d 453, 467-468, recognized that in an era of mass production and complex marketing methods the traditional standard of negligence was insufficient to govern the obligations of manufacturer to consumer, so should we acknowledge that some adaptation of the rules of causation and liability may be appropriate in these recurring circumstances. The Restatement comments that modification of the *Summers* rule may be necessary in a situation like that before us. (See fn. 16, ante.)

The most persuasive reason for finding plaintiff states a cause of action is that advanced in *Summers*: as between an innocent plaintiff and negligent defendants, the latter should bear the cost of the injury. Here, as in *Summers*,

plaintiff is not at fault in failing to provide evidence of causation, and although the absence of such evidence is not attributable to the defendants either, their conduct in marketing a drug the effects of which are delayed for many years played a significant role in creating the unavailability of proof.

From a broader policy standpoint, defendants are better able to bear the cost of injury resulting from the manufacture of a defective product. As was said by Justice Traynor in *Escola*, "[t]he cost of an injury and the loss of time or health may be an overwhelming misfortune to the person injured, and a needless one, for the risk of injury can be insured by the manufacturer and distributed among the public as a cost of doing business." (24 Cal.2d p. 462; see also Rest.2d Torts, § 402A, com. c, pp. 349-350.) The manufacturer is in the best position to discover and guard against defects in its products and to warn of harmful effects; thus, holding it liable for defects and failure to warn of harmful effects will provide an incentive to product safety. (Cronin v. J.B.E. Olson Corp. (1972) 8 Cal.3d 121, 129; Beech Aircraft Corp. v. Superior Court (1976) 61 Cal.App.3d 501, 522-523.) These considerations are particularly significant where medication is involved, for the consumer is virtually helpless to protect himself from serious, sometimes permanent, sometimes fatal, injuries caused by deleterious drugs.

Where, as here, all defendants produced a drug from an identical formula and the manufacturer of the DES which caused plaintiff's injuries cannot be identified through no fault of plaintiff, a modification of the rule of *Summers* is warranted. As we have seen, an undiluted *Summers* rationale is inappropriate to shift the burden of proof of causation to defendants because if we measure the chance that any particular manufacturer supplied the injury-causing product by

the number of producers of DES, there is a possibility that none of the five defendants in this case produced the offending substance and that the responsible manufacturer, not named in the action, will escape liability.

But we approach the issue of causation from a different perspective: we hold it to be reasonable in the present context to measure the likelihood that any of the defendants supplied the product which allegedly injured plaintiff by the percentage which the DES sold by each of them for the purpose of preventing miscarriage bears to the entire production of the drug sold by all for that purpose. Plaintiff asserts in her briefs that Eli Lilly and Company and 5 or 6 other companies produced 90 percent of the DES marketed. If at trial this is established to be the fact, then there is a corresponding likelihood that this comparative handful of producers manufactured the DES which caused plaintiff's injuries, and only a 10 percent likelihood that the offending producer would escape liability.[28]

If plaintiff joins in the action the manufacturers of a substantial share of the DES which her mother might have taken, the injustice of shifting the burden of proof to defendants to demonstrate that they could not have made the substance which injured plaintiff is significantly diminished. While 75 to 80 percent of the market is suggested as the

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[28]The Fordham Comment explains the connection between percentages of market share and liability as follows: "[I]f X Manufacturer sold one-fifth of all the DES prescribed for pregnancy and identification could be made in all cases, X would be the sole defendant in approximately one-fifth of all cases and liable for all the damages in those cases. Under alternative liability, X would be joined in all cases in which identification could not be made, but liable for only one-fifth of the total damages in these cases. X would pay the same amount either way. Although the correlation is not, in practice, perfect [footnote omitted], it is close enough so that defendants' objections on the ground of fairness lose their value." (Fordham Comment, supra, at p. 94.)

requirement by the Fordham Comment (at p. 996), we hold only that a substantial percentage is required.

The presence in the action of a substantial share of the appropriate market also provides a ready means to apportion damages among the defendants. Each defendant will be held liable for the proportion of the judgment represented by its share of that market unless it demonstrates that it could not have made the product which caused plaintiff's injuries. In the present case, as we have seen, one DES manufacturer was dismissed from the action upon filing a declaration that it had not manufactured DES until after plaintiff was born. Once plaintiff has met her burden of joining the required defendants, they in turn may cross-complain against other DES manufacturers, not joined in the action, which they can allege might have supplied the injury-causing product.

Under this approach, each manufacturer's liability would approximate its responsibility for the injuries caused by its own products. Some minor discrepancy in the correlation between market share and liability is inevitable; therefore, a defendant may be held liable for a somewhat different percentage of the damage than its share of the appropriate market would justify. It is probably impossible, with the passage of time, to determine market share with mathematical exactitude. But just as a jury cannot be expected to determine the precise relationship between fault and liability in applying the doctrine of comparative fault (Li v. Yellow Cab Co. (1975) 13 Cal.3d 804) or partial indemnity (American Motorcycle Assn. v. Superior Court (1978) 20 Cal.3d 578), the difficulty of apportioning damages among the defendant producers in exact relation to their market share does not seriously militate against the rule we adopt. As we said in *Summers* with regard to the liability of independent tortfeasors, where a correct division of liability

cannot be made "the trier of fact may make it the best it can." (33 Cal.2d at p. 88.)

We are not unmindful of the practical problems involved in defining the market and determining market share,[29] but these are largely matters of proof which properly cannot be determined at the pleading stage of these proceedings. Defendants urge that it would be both unfair and contrary to public policy to hold them liable for plaintiff's injuries in the absence of proof that one of them supplied the drug responsible for the damage. Most of their arguments, however, are based upon the assumption that one manufacturer would be held responsible for the products of another or for those of all other manufacturers if plaintiff ultimately prevails. But under the rule we adopt, each manufacturer's liability for an injury would be approximately equivalent to the damages caused by the DES it manufactured.[30]

The judgments are reversed.

Mosh, *J.*

We Concur:

Bird, *C.J.*

Newman, *J.*

*White, *J.*

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[29]Defendants assert that there are no figures available to determine market share, that DES was provided for a number of uses other than to prevent miscarriage and it would be difficult to ascertain what proportion of the drug was used as a miscarriage preventative, and that the establishment of a time frame and area for market share would pose problems.

[30]The dissent concludes by implying the problem will disappear if the Legislature appropriates funds "for the education, identification, and screening of persons exposed to DES." While such a measure may arguably be helpful in the abstract, it does not address the issue involved here: damages for injuries which have been or will be suffered. Nor, as a principle, do we see any justification for shifting the financial burden for such damages from drug manufactuers to the taxpayers of California.

*Assigned by the Chairman of the Judicial Council.

SINDELL v. ABBOTT LABORATORIES
ROGERS v. REXALL DRUG CO.
L.A. 31063

DISSENTING OPINION BY RICHARDSON, J.

I respectfully dissent. In these consolidated cases the majority adopts a wholly new theory which contains these ingredients: The plaintiffs were not alive at the time of the commission of the tortious acts. They sue a generation later. They are permitted to receive substantial damages from multiple defendants without any proof that any defendant caused or even probably caused plaintiffs' injuries.

Although the majority purports to change only the required burden of proof by shifting it from plaintiffs to defendants, the effect of its holding is to guarantee that plaintiffs will prevail on the causation issue because defendants are no more capable of disproving factual causation than plaintiffs are of proving it. "Market share" liability thus represents a new high water mark in tort law. The ramifications seem almost limitless, a fact which prompted one recent commentator, in criticizing a substantially identical theory, to conclude that "Elimination of the burden of proof as to identification [of the manufacturer whose drug injured plaintiff] would impose a liability which would exceed absolute liability." (Coggins, *Industry-Wide Liability* (1979) 13 Suffolk L.Rev. 980, 998, fn. omitted; see also, pp. 1000-1001.) In my view, the majority's departure from traditional tort doctrine is unwise.

The applicable principles of causation are very well established. A leading torts scholar, Dean Prosser, has authoritatively put it this way: "An *essential* element of the plaintiff's cause of action for negligence, *or for that matter for any other tort,* is that there be some reasonable connection between the act or omission of the defendant and

the damage which the plaintiff has suffered." (Prosser, Torts (4th ed. 1971) § 41, p. 236, italics added.) With particular reference to the matter before us, and in the context of products liability, the requirement of a causation element has been recognized as equally fundamental. "It is clear that any holding that a producer, manufacturer, seller, or a person in a similar position, is liable for injury caused by a particular product, must necessarily be predicated upon proof that the product in question was one for whose condition the defendant was in some way responsible. Thus, for example, if recovery is sought from a manufacturer, *it must be shown that he actually was the manufacturer of the product which caused the injury; . . .*" (1 Hursh & Bailey, American Law of Products Liability (2d ed. 1974) § 1:41, p. 125, italics added; accord, *Prosser*, supra, § 103, at pp. 671-672; 2 Dooley, Modern Tort Law (1977) § 32.03, p. 243.) Indeed, an inability to prove this causal link between defendant's conduct and plaintiff's injury has proven fatal in prior cases brought against manufacturers of DES by persons who were situated in positions identical to those of plaintiffs herein. (See McCreery v. Eli Lilly & Co. (1978) 87 Cal.App.3d 77, 82; Gray v. United States (D.Tex. 1978) 445 F.Supp. 337, 338.)

The majority now expressly abandons the foregoing traditional requirement of some causal connection between defendants' act and plaintiffs' injury in the creation of its new modified industry-wide tort. Conceptually, the doctrine of absolute liability which heretofore in negligence law has substituted only for the requirement of a breach of defendant's duty of care, under the majority's hand now subsumes the additional necessity of a causal relationship.

According to the majority, in the present case plaintiffs have openly conceded that they are unable to identify the particular entity which manufactured the drug consumed by

their mothers. In fact, plaintiffs have joined only *five* of the approximately *two hundred* drug companies which manufactured DES. Thus, the case constitutes far more than a mere factual variant upon the theme composed in Summers v. Tice (1948) 33 Cal.2d 80, where plaintiff joined as co-defendants the *only* two persons who could have injured him. As the majority must acknowledge, our *Summers* rule applies only to cases in which ". . . it is proved that harm has been caused to the plaintiff by . . . one of [the named defendants], but there is uncertainty as to which one has caused it, . . ." (Rest.2d Torts, § 433B, subd. (3).) In the present case, in stark contrast, it remains wholly speculative and conjectural whether *any* of the five named defendants actually caused plaintiffs' injuries.

The fact that plaintiffs cannot tie defendants to the injury-producing drug does not trouble the majority for it declares that the *Summers* requirement of proof of actual causation by a named defendant is satisfied by a joinder of those defendants who have *together* manufactured *"a substantial percentage"* of the DES which has been marketed. Notably lacking from the majority's expression of its new rule, unfortunately, is any definition or guidance as to what should constitute a "substantial" share of the relevant market. The issue is entirely open-ended and the answer, presumably, is anyone's guess.

Much more significant, however, is the consequence of this unprecedented extension of liability. Recovery is permitted from a handful of defendants *each* of whom *individually* may account for a comparatively small share of the relevant market, so long as the *aggregate* business of those who have been sued is deemed "substantial." In other words, a particular defendant may be held proportionately liable *even though mathematically it is much more likely than not that it played no role whatever in causing plaintiffs'*

injuries. Plaintiffs have strikingly capsulated their reasoning by insisting ". . . that while one manufacturer's product may not have injured a particular plaintiff, we can assume that it injured a different plaintiff and all we are talking about is a mere matching of plaintiffs and defendants." (Counsel's letter (Oct. 16, 1979) p. 3.) In adopting the foregoing rationale the majority rejects over 100 years of tort law which required that before tort liability was imposed a "matching" of defendant's conduct and plaintiff's injury was absolutely essential. Furthermore, in bestowing on plaintiffs this new largess the majority sprinkles the rain of liability upon all the joined defendants alike—those who may be tortfeasors and those who may have had nothing at all to do with plaintiffs' injury—and an added bonus is conferred. Plaintiffs are free to pick and choose their targets.

The "market share" thesis may be paraphrased. Plaintiffs have been hurt by *someone* who made DES. Because of the lapse of time no one can prove who made it. Perhaps it was not the named defendants who made it, but they did make some. Although DES was apparently safe at the time it was used, it was subsequently proven unsafe as to some daughters of some users. Plaintiffs have suffered injury and defendants are wealthy. There should be a remedy. Strict products liability is unavailable because the element of causation is lacking. Strike that requirement and label what remains "alternative" liability, "industry-wide" liability, or "market share" liability, proving thereby that if you hit the square peg hard and often enough the round holes will really become square, although you may splinter the board in the process.

The foregoing result is directly contrary to long established tort principles. Once again, in the words of Dean Prosser, the applicable rule is: "[Plaintiff] must introduce evidence which affords a reasonable basis for the conclusion

that it is more likely than not that the conduct of the defendant was a substantial factor in bringing about the result. *A mere possibility of such causation is not enough;* and when the matter remains one of pure speculation or conjecture, or the probabilities are at best evenly balanced, it becomes the duty of the court to direct a verdict for the defendant." (*Prosser*, supra, § 41, at p. 241, italics added, fns. omitted.) Under the majority's new reasoning, however, a defendant is fair game if it happens to be engaged in a similar business and causation is *possible*, even though remote.

In passing, I note the majority's dubious use of market share data. It is perfectly proper to use such information to assist in proving, circumstantially, that a particular defendant probably caused plaintiffs' injuries. Circumstantial evidence may be used as a basis for proving the requisite probable causation. (*Id.*, at p. 242.) The majority, however, authorizes the use of such evidence for an entirely different purpose, namely, to impose and allocate liability among multiple defendants only one of whom *may* have produced the drug which injured plaintiffs. Because this use of market share evidence does not implicate *any* particular defendant, I believe such data are entirely irrelevant and inadmissible, and that the majority errs in such use. In the absence of some statutory authority there is no legal basis for such use.

Although seeming to acknowledge that imposition of liability upon defendants who probably did not cause plaintiffs' injuries is unfair, the majority justifies this inequity on the ground that "each manufacturer's liability for an injury would be approximately equivalent to the damages caused by the DES it manufactured." (*Ante*, p. .... [maj. opn., at p. 35].) In other words, because each defendant's liability is proportionate to its market share, supposedly "each manufacturer's liability would approximate its re-

sponsibility for the injuries caused by his own products." (*Ante*, p. .... [maj. opn., at p. 33].) The majority dodges the "practical problems" thereby presented, choosing to describe them as "matters of proof." However, the difficulties, in my view, are not so easily ducked, for they relate not to evidentiary matters but to the fundamental question of liability itself.

Additionally, it is readily apparent that "market share" liability will fall unevenly and disproportionately upon those manufacturers who are amenable to suit in California. On the assumption that no other state will adopt so radical a departure from traditional tort principles, it may be concluded that under the majority's reasoning those defendants who are brought to trial in this state will bear effective joint responsibility for 100 percent of plaintiffs' injuries despite the fact that their "substantial" aggregate market share may be considerably less. This undeniable fact forces the majority to concede that, "a defendant may be held liable for a somewhat different percentage of the damage than its share of the appropriate market would justify." (*Ante*, p. ... [maj. opn., at p. 33].) With due deference, I suggest that the complete unfairness of such a result in a case involving only five of two hundred manufacturers is readily manifest.

Furthermore, several other important policy considerations persuade me that the majority holding is both inequitable and improper. The injustice inherent in the majority's new theory of liability is compounded by the fact that plaintiffs who use it are treated far more favorably than are the plaintiffs in routine tort actions. In most tort cases plaintiff knows the identity of the person who has caused his injuries. In such a case, plaintiff, of course, has no option to seek recovery from an entire industry or a "substantial" segment thereof, but in the usual instance can recover, if at all, only from the particular defendant causing

injury. Such a defendant may or may not be either solvent or amenable to process. Plaintiff in the ordinary tort case must take a chance that defendant can be reached and can respond financially. On what principle should those plaintiffs who wholly fail to prove any causation, an essential element of the traditional tort cause of action, be rewarded by being offered both a wider selection of potential defendants and a greater opportunity for recovery?

The majority attempts to justify its new liability on the ground that defendants herein are "better able to bear the cost of injury resulting from the manufacture of a defective product." (*Ante*, p. ... [maj. opn., at p. 30].) This "deep pocket" theory of liability, fastening liability on defendants presumably because they are rich, has understandable popular appeal and might be tolerable in a case disclosing substantially stronger evidence of causation than herein appears. But as a general proposition, a defendant's wealth is an unreliable indicator of fault, and should play no part, at least consciously, in the legal analysis of the problem. In the absence of proof that a particular defendant caused or at least probably caused plaintiff's injuries, a defendant's ability to bear the cost thereof is no more pertinent to the underlying issue of liability than its "substantial" share of the relevant market. A system priding itself on "*equal* justice under law" does not flower when the *liability* as well as the *damage* aspect of a tort action is determined by a defendant's wealth. The inevitable consequence of such a result is to create and perpetuate two rules of law—one applicable to wealthy defendants, and another standard pertaining to defendants who are poor or who have modest means. Moreover, considerable doubts have been expressed regarding the ability of the drug industry, and especially its smaller members, to bear the substantial economic costs (from both damage awards and high insurance premiums)

inherent in imposing an industry-wide liability. (See Coggins, supra, 13 Suffolk L.Rev. at pp. 1003-1006, 1010-1011.)

An important and substantial countervailing public policy in defendants' favor was very recently expressed in a similar DES case, McCreery v. Eli Lilly & Co., supra, 87 Cal.App.3d 77, 86-87. Although the majority herein impliedly rejects the appellate court's holding, in my opinion pertinent language of the *McCreery* court, based upon the Restatement of Torts and bearing on the majority's "market share" theory, is well worth repeating: "Application of the comments to the Restatement Second of Torts, section 402A, to this situation compels a rejection of the imposition of liability. As the comment states, '. . . It is also true in particular of many new or experimental drugs as to which, because of lack of time and opportunity for sufficient medical experience, there can be no assurance of safety, or perhaps even of purity of ingredients, but such experience as there is justifies the marketing and use of the drug notwithstanding a medically recognizable risk. The seller of such products, again, with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not to be held to strict liability for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk.' (Rest.2d Torts, § 402A, com. k.) *This section implicitly recognizes the social policy behind the development of new pharmaceutical preparations.* As one commentator states, '[t]he social and economic benefits from mobilizing the industry's resources in the war against disease and in reducing the costs of medical care are potentially enormous. The development of new drugs in the last three decades has already

resulted in great social benefits. The potential gains from further advances remain large. To risk such gains is unwise. Our major objective should be to encourage a continued high level of industry investment in pharmaceutical R & D [research and development].' (Schwartzman, The Expected Return from Pharmaceutical Research: Sources of New Drugs and the Profitability of R & D Investment (1975) p. 54.)" (McCreery v. Eli Lilly & Co., supra, 87 Cal.App.3d 77, 86-87, italics added; see also Coggins, supra, 13 Suffolk L.Rev. at p. 1004.)

In the present case the majority imposes liability more than 20 years after ingestion of drugs which at the time they were used, after careful testing, had the full approval of the United States Food and Drug Administration. It seems to me that liability in the manner created by the majority must inevitably inhibit, if not the research or development, at least the dissemination of new pharmaceutical drugs. Such a result, as explained by the Restatement, is wholly inconsistent with traditional tort theory.

I also suggest that imposition of so sweeping a liability may well prove to be extremely shortsighted from the standpoint of broad social policy. Who is to say whether, and at what time and in what form, the drug industry upon which the majority now fastens this blanket liability, may develop a miracle drug critical to the diagnosis, treatment, or, indeed, cure of the very disease in question? It is counterproductive to inflict civil damages upon *all* manufacturers for the side effects and medical complications which surface in the children of the users a generation after ingestion of the drugs, particularly when, at the time of their use, the drugs met every fair test and medical standard then available and applicable. Such a result requires of the pharmaceutical industry a foresight, prescience and anticipation far beyond the most exacting standards of the relevant scientific dis-

ciplines. In effect, the majority requires the pharmaceutical research laboratory to install a piece of new equipment—the psychic's crystal ball.

I am not unmindful of the serious medical consequences of plaintiffs' injuries, and the equally serious implications to the class which she purports to represent. In balancing the various policy considerations, however, I also observe that the incidence of vaginal cancer among "DES daughters" has been variously estimated at one-tenth of 1 percent to four-tenths of 1 percent. (13 Suffolk L.Rev., supra, p. 999, fn. 92.) These facts raise some penetrating questions. Ninety-nine plus percent of "DES daughters" have never developed cancer. Must a drug manufacturer to escape this blanket liability wait for a generation of testing before it may disseminate drugs? If a drug has beneficial purposes for the majority of users but harmful side-effects are later revealed for a small fraction of consumers, will the manufacturer be absolutely liable? If adverse medical consequences, wholly unknown to the most careful and meticulous of present scientists, surface in *two* or *three* generations, will sense and reality combine to warn that a "market share" theory goes too far. Legally, it expects too much.

I believe that the scales of justice tip against imposition of this new liability because of the foregoing elements of unfairness to some defendants who may have had nothing whatever to do with causing any injury, the unwarranted preference created for this particular class of plaintiffs, the violence done to traditional tort principles by the drastic expansion of liability proposed, the injury threatened to the public interest in continued unrestricted basic medical research as stressed by the Restatement, and the other reasons heretofore expressed.

The majority's decision effectively makes the entire drug industry (or at least its California members) an insurer of

all injuries attributable to defective drugs of uncertain or unprovable origin, including those injuries manifesting themselves a generation later, and regardless of whether particular defendants had any part whatever in causing the claimed injury. Respectfully, I think this is unreasonable overreaction for the purpose of achieving what is perceived to be a socially satisfying result.

Finally, I am disturbed by the broad and ominous ramifications of the majority's holding. The law review comment, which is the wellspring of the majority's theory, conceding the widespread consequences of industry-wide liability, openly acknowledges that "The DES cases are only the tip of an iceberg." (Comment, *DES and a Proposed Theory of Enterprise Liability* (1978) 46 Fordham L.Rev. 963, 1007.) Although the pharmaceutical drug industry may be the first target of this new sanction, the majority's reasoning has equally threatening applications to many other areas of business and commercial activities.

Given the grave and sweeping economic, social, and medical effects of "market share" liability, the policy decision to introduce and define it should rest not with us, but with the Legislature which is currently considering not only major statutory reform of California product liability law in general, but the DES problem in particular. (See Sen. Bill No. 1392 (1979-1980 Reg. Sess.), which would establish and appropriate funds for the education, identification, and screening of persons exposed to DES, and would prohibit health care and hospital service plans from excluding or limiting coverage to persons exposed to DES.) An alternative proposal for administrative compensation, described as "a limited version of no-fault products liability" has been suggested by one commentator. (*Coggins*, supra, 13 Suffolk L.Rev. at pp. 1019-1021.) Compensation under such a plan would be awarded by an administrative tribunal

from funds collected "via a tax paid by all manufacturers." (P. 1020, fn. omitted.) In any event, the problem invites a legislative rather than an attempted judicial solution.

I would affirm the judgments of dismissal.

Richardson, *J.*

We Concur:

Clark, *J.*

Manuel, *J.*

APPENDIX B.

Opinion of the California Court of Appeal.

In the Court of Appeal of the State of California, Second Appellate District, Division Three.

Judith Sindell, Plaintiff and Appellant, v. Abbott Laboratories, et al., Defendants and Respondents. Maureen Rogers, Plaintiff and Appellant, v. Rexall Drug Company, et al., Defendants and Respondents. 2d Civil No. 51845, (Los Angeles County, Super. Ct. No. C 169 127). 2d Civil No. 51875, (Ventura County, Super. Ct. No. 61220).

Filed: September 21, 1978 and modified on October 19, 1978.

APPEAL from judgments (orders of dismissal) of the Superior Court of Los Angeles County (No. 51845). Jerry Pacht and Robert I. Weil, Judges. Reversed.

APPEAL from judgments (orders of dismissal) of the Superior Court of Ventura County (No. 51875). Steven J. Stone, Judge. Reversed.

Donnenfeld & Brent and Jason G. Brent for Appellant Judith Sindell.

Heily, Blase, Ellison & Wellcome and Jay H. Sorensen for Appellant Maureen Rogers.

Morgan, Wenzel & McNicholas, Darryl L. Dmytriw, Lord, Bissel & Brook and Hugh L. Moore for Respondent Abbott Laboratories.

Crosby, Heafey, Roach & May, Richard J. Heafey, Peter W. Davis and John E. Carne for Respondent Eli Lilly and Company.

Adams, Duque & Hazeltine, Richard C. Field and David L. Bacon for Respondent Rexall Drug Company.

Haight, Dickson, Brown, Bonesteel & Rigg, Robert L. Dickson, Roy G. Weatherup and Hall R. Marston for

Respondents E. R. Squibb & Sons, Inc. and Upjohn Company.

INTRODUCTORY STATEMENT

These appeals are from dismissals and judgments entered after the sustaining of defendants' demurrers to actions brought by Judith Sindell (hereinafter Sindell) and Maureen Rogers (hereinafter Rogers) for personal injuries allegedly resulting from prenatal exposure to diethylstilbestrol (DES). Although arising out of actions in the Los Angeles County and Ventura County Superior Courts, the appeals are consolidated because of common issues of fact and law.

In both actions, defendant drug manufacturers demurred on the ground that the complaints failed to state a cause of action in that there was no identification of the particular defendant which manufactured the DES that allegedly caused harm to plaintiffs; it appears that it was on this premise only that the demurrers were sustained without leave to amend. For the reasons discussed below, we reverse the judgments of dismissal.

STATEMENT OF THE CASE

Both Sindell and Rogers sue on their own behalf and as representatives of all women residing in California who are similarly situated, although Sindell limits her representative status to the portion of her complaint seeking certain equitable relief. The complaints, which are substantially identical, allege that the prerequisites for maintaining plaintiff and defendant class actions are satisfied.[1] Both actions are for money damages and equitable relief and seek to hold defendants individually and jointly liable for unlawfully manufacturing, marketing, and promoting DES. The com-

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[1]We do not address the complicated class action issues raised by the complaints as such a discussion is not necessary to our opinion.

plaints allege that DES, which was ingested by plaintiffs' mothers as a miscarriage preventative, has caused plaintiffs to develop precancerous and cancerous tumors and lesions.

Sindell's Complaint

In her complaint, Sindell alleges that she has developed precancerous lesions or tumors of the vagina, cervix, and breast and a cancerous bladder tumor which has been surgically removed. Her complaint sets forth ten causes of action, each of which is alleged to arise from the individual and concerted action of the defendants in the manufacture and marketing of DES. The causes of action charge express and implied agreements among defendants and collaboration in, reliance upon, and adoption of each other's testing and marketing methods with respect to the subject drug.

In her first seven causes of action, Sindell seeks to hold defendants liable on the following theories: negligence, strict products liability, lack of informed consent, breach of express warranties, breach of implied warranties, fraud, and violations of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 301 et seq.).

In what is denominated an eighth cause of action, Sindell alleges that all activities engaged in by the defendants were the result of joint and concerted enterprise, that there existed a common and mutually agreed upon formula for the drug, that the various brands of DES were marketed by the defendants as being fungible and interchangeable with all other brands of the drug, and that there was a pharmaceutical practice of filling prescriptions of DES with a brand other than that prescribed.

The ninth cause of action sounds in conspiracy, and the tenth relates to the class aspects of the action. Nowhere in Sindell's complaint does she identify the specific manufacturer of the DES ingested by her mother.

The general demurrers of defendants Rexall Drug Company, E. R. Squibb & Sons, Inc., and Upjohn Company were sustained without leave to amend, all on the ground that Sindell had failed in her complaint to identify the specific manufacturer of the DES which allegedly injured her. Defendant Abbott Laboratories' general demurrer was sustained with 30 days leave to amend, the court noting the absence of an "allegation that any product manufactured by demurring defendant caused any harm to plaintiff." Sindell, however, failed to thereafter amend her complaint. Defendant Eli Lilly and Company's motion for summary judgment was treated as a demurrer and sustained without leave to amend on the same ground as stated previously — that Sindell could not name an individual defendant.

Sindell appeals from the orders of dismissal which were subsequently entered in favor of the above named defendants.[2]

Rogers' Complaint

Rogers alleges that she has developed cervical cancer and precancerous lesions or tumors of the vagina and cervix. She also alleges that defendant manufacturers of DES have acted both individually and jointly, their "joint and concerted" actions including, but not limited to, joint testing, marketing, and promotional activity, as well as mutual exploitation of the common formula for the drug, which in turn led to the pharmaceutical practice of treating the various brands of DES as being interchangeable with one another.

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[2]The record on appeal reflects that Sindell also appealed from an order dismissing defendant Warner Lambert/Parke Davis Company following the sustaining of its demurrer without leave to amend. The parties, however, have since stipulated to a dismissal of this defendant from the action.

Rogers' first amended complaint contains the following six causes of action: negligence, strict products liability, breach of express warranties, breach of implied warranties, false representations, and violations of the Federal Food, Drug, and Cosmetic Act.

By amendment to her first amended complaint, Rogers has identified defendant Eli Lilly and Company as the manufacturer of the DES ingested by her mother.

The general demurrer of defendant Rexall Drug Company was sustained without leave to amend "because Rexall is nowhere in the pleadings shown to have provided or purveyed the particular drug which affected plaintiff [Rogers]. . . ." The joint demurrer of defendants E. R. Squibb & Sons, Inc. and Upjohn Company was sustained without leave to amend on the stated ground that Rogers' first amended complaint failed to allege facts sufficient to sustain a cause of action.[3] Rogers appeals from the orders of dismissal subsequently entered in favor of these defendants. Since Rogers identified Eli Lilly and Company as the producer of the DES taken by her mother, it remains a defendant in her case.[4]

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[3]Although defendants E. R. Squibb & Sons, Inc. and Upjohn Company jointly demurred on a number of grounds, including bar of the statute of limitations, their supporting papers stated that "the bottom line of this Demurrer, indeed of this case, is whether a plaintiff can maintain a cause of action against a product manufacturer and distributor without alleging that it actually used that manufacturer's product!" Thus, while the trial court was not specific as to its reasons for sustaining these defendants' demurrer, we assume for the purposes of this discussion that its ruling was based on the same ground as the other defendants prevailed on, i.e., failure of the plaintiff to limit herself to an individual defendant. For the reasons discussed later in this opinion, we deem it inappropriate at this point in the litigations to discuss the other possible bases for the sustaining of any of these demurrers, except insofar as they raise the limitations question.

[4]Rogers also appealed from a summary judgment which was granted to Miles Laboratories, Incorporated on the basis of an affidavit establishing that it never produced DES as a miscarriage preventative. Subsequent to filing her notice of appeal, however, Rogers stipulated in the superior court to a dismissal of Miles from the action.

DISCUSSION

Preliminary to our discussion, we note that since these appeals are before us on general demurrers, we must assume all allegations of fact set forth in the complaints to be true. (*Landeros v. Flood* (1976) 17 Cal.3d 399, 407; *Bayer v. Suttle* (1972) 23 Cal.App.3d 361, 363.) The question of plaintiffs' ability to prove these allegations, or the possible difficulty in making such proof, does not concern the reviewing court. (*Landeros v. Flood, supra; Alcorn v. Anbro Engineering, Inc.* (1970) 2 Cal.3d 493, 496.) Furthermore, "A general demurrer admits not only the facts expressly alleged but also facts essential to a cause of action which the facts alleged supply by implication or inference." (*Harvey v. City of Holtville* (1969) 271 Cal.App.2d 816, 819.)

Being thus directed by the case law noted, we observe that both the Sindell and Rogers complaints contain factual allegations which, if proven, would establish that defendants are both individually and jointly responsible for plaintiffs' injuries in that they acted in both their individual capacities and in concert in the doing of the wrongful acts which caused those injuries. This is the state of the record before us as the reviewing court. As such, the doctrines of concerted action and alternative liability enable these complaints to stand at this stage of the proceedings.

Defendants' parade of horribles and fears of "collectivized liability" or "enterprise liability" are groundless in the light of our narrow holding embracing these two California doctrines.[5]

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[5]As we find adequate support for our holding in existing California law, we reject plaintiffs' invitation that we adopt for this state the so-called "enterprise liability" theory. However, for an excellent discussion of the possible application of that theory to DES cases, see Note. *Des and a Proposed Theory of Enterprise Liability* (1978) 46 Fordham L.Rev. 963.

The Concerted Action Theory

Section 876 of the Restatement of Torts, which is entitled "Persons Acting in Concert," provides in pertinent part as follows:

> "For harm resulting to a third person from the tortious conduct of another, a person is liable if he
>
> "....
>
> "(b) knows that the other's conduct constitutes a breach of duty and gives substantial assistance or encouragement to the other so to conduct himself, or
>
> "(c) gives substantial assistance to the other in accomplishing a tortious result and his own conduct, separately considered, constitutes a breach of duty to the third person."

It has been noted that the rule as stated in the above section of the Restatement is clearly the law of California. (*Pasadena Unified Sch. Dist. v. Pasadena Federation of Teachers* (1977) 72 Cal.App.3d 100, 113, citing *Loeb v. Kimmerle* (1932) 215 Cal. 143, 150.)

Witkin states that the Restatement's definition of "joint tortfeasors" applies not only to those who act in concert to accomplish some common goal or plan and thereby cause injury, but also to "those who order, direct or permit others to do the act, *and who give assistance or encouragement.*" (Italics added.) (4 Witkin, Summary of Cal. Law (8th ed. 1974) Torts, § 30, pp. 2329-2330.)

Harper and James cite section 876 of the Restatement of Torts as universal authority for the proposition that wrongdoers who act in concert are jointly and severally liable. (1 Harper & James, Law of Torts (1956) § 10.1, p. 698.)

In commenting on the doctrine of concerted action, Prosser states that "All those who, in pursuance of a common plan or design to commit a tortious act, actively take part

in it, or further it by cooperation or request, or who lend aid or encouragement to the wrongdoer, or ratify and adopt his acts done for their benefit, are equally liable with him. [¶] Express agreement is not necessary, and all that is required is that there be a tacit understanding. . . ." (Fns. omitted.) (Prosser, Law of Torts (4th ed. 1971) § 46, p. 292; see also Prosser, *Joint Torts and Several Liability* (1937) 25 Cal.L.Rev. 413, 429-430.) But Prosser further notes that in pleading a cause of action based on concerted action, "It is . . . essential that each particular defendant who is to be charged with responsibility shall be proceeding tortiously, which is to say with intent to commit a tort, or with negligence. One who innocently, and carefully, does an act which furthers the tortious purpose of another is not acting in concert with him." (Fn. omitted.) (Prosser, Law of Torts, *supra*, at p. 292; see also Rest., Torts, *supra*, § 875, com. a.)

This court recognizes more than a half-dozen California cases which have applied, in a variety of factual situations, the doctrine of concerted action. Most notable among these are: *Loeb v. Kimmerle*, *supra*, 215 Cal. 143, 150-151 (a personal injuries action); *The Weinberg Co. v. Bixby* (1921) 185 Cal. 87, 93, 106-107 (action for wrongful diversion of flood waters); *Orser v. George* (1967) 252 Cal.App.2d 660, 666-669 (wrongful death action); *Agovino v. Kunze* (1960) 181 Cal.App.2d 591 (action for personal injuries); and *Meyer v. Thomas* (1937) 18 Cal.App.2d 299, 306 (action for conversion of a promissory note).

Orser v. George, *supra*, 252 Cal. App.2d 660, summarizes California case law regarding the doctrine of concerted action and explains the rationale of the use of that theory to establish the element of causation.

Orser was a wrongful death action in which the trial court had granted a summary judgment in favor of two of three

potentially liable defendants.[6] The three defendants were hunters who were alleged to have engaged in the tortious conduct of firing their guns at mudhens in the direction of the decedent. Two of the three defendants were alleged to have been alternately firing the same gun, a pistol, the bullet from which was subsequently determined to have killed the decedent. The third defendant could not have fired the fatal bullet, but he was alleged to have been shooting with a rifle in the same line of fire as the other two defendants. (*Id.* at pp. 664-666) As there was a triable issue of fact as to which of the two defendants using the pistol had fired the fatal shot, the appellate court reversed the summary judgment which had been granted as to one of them. (*Id.* at p. 668.) In addition, the court reversed, on a theory of concert, a summary judgment which had been entered in favor of the third, rifle-shooting defendant. The reasoning of the appellate court (which emphasized that it was concerned only with possibilities and not actual proof) was that triable issues remained as to whether the third defendant knew that his companions' conduct constituted a breach of duty owed the decedent and, further, whether his own tortious conduct in firing the rifle in the direction of the decedent had provided the other defendants "substantial 'assistance or encouragement.' " (*Id.* at p. 668, paraphrasing Rest., Torts, *supra*, § 876, subds. (b) and (c).)

We note that, in so holding, the court in *Orser* indicated that Prosser's definition of concerted action (quoted above) is in line with both the Restatement's rule regarding joint action by tortfeasors and our Supreme Court's explication of that rule in a similar case, *Summers v. Tice* (1948) 33

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[6]there were actually several additional defendants named in *Orser*, but their involvement is not relevant to the issues before us.

Cal.2d 80, 85 (See discussion thereof, *infra*). (*Orser v. George, supra*, 252 Cal.App.2d 660, 667-668.)

The cases before us present a situation analogous to the one in *Orser*. Both the Sindell and Rogers complaints contain the identical allegation that the defendant drug manufacturers, "acting individually *and in concert*, promoted, approved, authorized, acquiesced in, and reaped profits from sales" of DES. (Italics ours.) In addition, similar language appears in both complaints to the effect that express and implied agreements existed between the defendants regarding the manufacture and marketing of DES and that the defendants collaborated in, relied upon, acquiesced in, ratified, adopted, and exploited each other's testing (or lack thereof), marketing techniques, and promotional campaigns. The culmination of the defendants' concerted action is seen in the allegation, again common to both complaints, that there existed a common and mutually agreed upon formula for DES which permitted defendants to promote the drug as a fungible commodity, resulting in the pharmaceutical practice which permitted the filling of prescriptions for DES with a brand other than that prescribed.

These allegations, together with others not here mentioned, satisfy the pleading requirements necessary to hold defendants jointly liable on a concerted action theory. The fact that every defendant named herein may not have manufactured the DES actually ingested by plaintiffs' mothers is not determinative since, as in *Orser*, the allegations indicate that each defendant gave "substantial 'assistance or encouragement' " to the tortious conduct of the others. (*Orser v. George, supra*, 252 Cal.App.2d 660, 668; see also Rest., Torts, *supra*, § 876, subds. (b) and (c).)

We reiterate that at this stage of the proceedings we are not concerned with the truth of plaintiffs' allegations or their ability to prove them. (*Alcorn v. Anbro Engineering, Inc.*,

supra, 2 Cal.3d 493, 496; cf. *Orser v. George*, *supra*, 252 Cal.App.2d at pp. 668-669.) Whether each defendant's conduct *actually* was a substantial factor in causing plaintiffs' injuries will be a question for the trier of fact. (Prosser, Law of Torts, *supra*, § 41, p. 240.)

Defendants cite numerous authorities[7] for the proposition that in a products liability action it must be shown that the defendant actually manufactured or sold the product which caused the plaintiff's injuries. This rule, however, is only one specific illustration of the general legal principle requiring a defendant to be the cause-in-fact of a plaintiff's harm. The doctrine of concerted action embodied in section 876 of the Restatement of Torts satisfies the requisite cause-in-fact element. As Prosser states, "The defendant's conduct is a cause of the event if it was a material element and a substantial factor in bringing it about." (Prosser, Law of Torts, *supra*, § 41, p. 240.) Thus, where concerted action is pled it is irrelevant whether the actual manufacturer of the product which caused the injury is identified. Indeed, in *Hall v. E. I. Du Pont De Nemours & Co., Inc.* (E.D.N.Y. 1972) 345 F.Supp. 353, 372, the court noted that "the issue of who 'caused' the injury is distinctly secondary to the fact that the group engaged in joint hazardous conduct."

By alleging concerted action by defendants in the production and marketing of DES, the pleadings, before us

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[7]See, e.g., *Sell v. Volkswagen of America, Inc.* (6th Cir. 1974) 505 F.2d 953, 955; *Wetzel v. Eaton Corporation* (D. Minn. 1973) 62 F.R.D. 22, 28; *Thompson-Hayward Chem. Co. v. Childress* (Ala. 1964) 169 So.2d 305, 309; Annotation, Products Liability: Necessity and Sufficiency of Identification of Defendant as Manufacturer or Seller of Product Alleged to Have Caused Injury (1973) 51 A.L.R.3d 1344, 1349; 63 American Jurisprudence Second, Products Liability, section 5, page 12; 1 Hursh & Bailey, American Law of Products Liability (2d ed. 1974) section 1:41, pages 125-126.

conform to the requirement stated in 1 Hursh & Bailey, American Law of Products Liability, *supra*, section 1:41, page 125, "that the product in question was one for whose condition the defendant was *in some way responsible*." (Italics added.)

Further, since our holding here is grounded upon plaintiffs' allegations of cooperation and joint control among the defendant manufacturers of DES, there is no basis to defendants' expressed fears that henceforth all manufacturers of similar products will be held liable when one has been found to have produced a defective product. To the contrary, it is the law of this state that a defendant will not be held liable if it did not produce a defective product. Here, however, defendants are alleged to have acted jointly and in concert in the manufacturing, testing, marketing, and promoting of DES; if plaintiffs' allegations can be proven, it will be established that each defendant did, in fact, produce a defective product.

The factors cited above distinguish our cases from *Wetzel v. Eaton Corporation, supra*, 62 F.R.D. 22, heavily relied upon by defendants. In *Wetzel*, the court granted a summary judgment to one of two manufacturers alleged to have supplied a defective tractor component for lack of evidentiary support showing that that manufacturer had supplied the part which allegedly caused the plaintiff's accident. (*Id.* at pp. 28-29.) Since there was nothing to indicate that the manufacturer seeking the summary judgment had behaved tortiously toward the plaintiff, the court refused to apply California law pertaining to the concerted action or alternative liability doctrines. (*Id.* at pp. 29-30.) Here, in contrast, it is alleged that *each* named defendant has engaged in tortious conduct toward each and every plaintiff. (See fn. 10, *infra*.)

Defendants assert that they did not owe any duty to plaintiffs because of the "unavoidably unsafe products" exception to the general rules pertaining to strict liability in tort. That exception is applicable to products which, "in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use." (Rest., 2d Torts, § 402A, com. k, p. 353.) "Such a product, properly prepared, and *accompanied by proper directions and warning*, is not defective . . . ." (*Id.* at pp. 353-354, italics added.) But whether the product in question here was "incapable of being made safe" is a matter of proof which cannot be resolved by inspection of the pleadings before us. We also note that both complaints contain allegations that DES was marketed without warning of the hazards apparently inherent in its use. Moreover, the rationale given for the "unavoidably unsafe products" exception is that the benefits attaching to certain potentially harmful products outweight the risks they pose. (*Id.* at p. 353.) In the cases at bench, it is alleged not only that defendants engaged in inadequate testing of DES, but also that whatever testing was done showed the drug to be totally ineffective as a miscarriage preventative.

Furthermore, we find unpersuasive defendants' assertions that drug manufacturers must receive more lenient treatment than other manufacturers in the area of products liability. Indeed, Justice Jackson specifically included the drug industry as subject to the duty to make adequate tests and give proper warnings in this passage from his oft-cited dissent in *Dalehite v. United States* (1953) 346 U.S. 15, 51-52: "[T]o an ever-increasing extent our population is dependent upon mass producers for its food and drink, its cures and complexions. . . . Such a dependent society . . . must require from manufacturers or producers increased integrity and caution as the only protection of its safety and well-

being. Purchasers cannot try out drugs to determine whether they kill or cure. . . . Where experiment or research is necessary to determine the presence or the degree of danger, the product must not be tried out on the public, nor must the public be expected to possess the facilities or the technical knowledge to learn for itself of inherent but latent dangers. The claim that a hazard was not foreseen is not available to one who did not use foresight appropriate to his enterprise."

The Alternative Liability Theory

In the landmark case of *Summers v. Tice, supra,* 33 Cal.2d 80, two hunters negligently fired their guns in the direction of the plaintiff at the same time. It was impossible to ascertain which of the defendants fired the shot which injured the plaintiff. (*Id.* at p. 84.) Under these circumstances, the court held that the defendants were jointly and severally liable unless they could absolve themselves, stating:

> "When we consider the relative position of the parties and the results that would flow if plaintiff was required to pin the injury on one of the defendants only, a requirement that the burden of proof on that subject be shifted to defendants becomes manifest. They are both wrongdoers—both negligent toward plaintiff. They brought about a situation where the negligence of one of them injured the plaintiff, hence it should rest with them each to absolve himself if he can. The injured party has been placed by defendants in the unfair position of pointing to which defendant caused the harm. If one can escape the other may also and plaintiff is remediless." (*Id.* at p. 86.)

Justice Traynor characterized the *Summers* burden of proof rule as "based on the policy that it is preferable to hold liable a negligent defendant who did not in fact cause

the injury than to deny an innocent plaintiff any remedy when it cannot be determined which of the defendants is responsible for the harm but it appears that one of them was." (*Vasquez v. Alameda* (1958) 49 Cal.2d 674, 682-683, fn. 2 (Traynor, J. dissentingcp; see also *Haft v. Lone Palm Hotel* (1970) 3 Cal.3d 756, 774, fn. 19.)

The shifting burden of proof rule enunciated in *Summers*, often referred to as the doctrine of alternative liability (see Prosser, Law of Torts, *supra*, § 41, p. 243), is logically applicable to at least the allegations set forth in Sindell's complaint.[8] Those allegations, if proven, would establish that each of the defendants before us has engaged in tortious behavior which created undue risks for the offspring of DES users.[9] Further, although Sindell did not specifically allege

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[8]Should Rogers succeed in proving her allegation that Eli Lilly and Company manufactured the particular brand of DES ingested by her mother, she will arguably be unable to rely on the alternative liability theory since, as is apparent, it requires that a plaintiff be ignorant of the source of his or her injury. Proof that Eli Lilly and Company produced the DES taken by Rogers' mother would not, however, prevent her from having recourse to the concerted action theory discussed above. The distinction is that the alternative liability concept contemplates a situation where two or more defendants have behaved tortiously but fewer than all have actually caused the injury, whereas the theory of concerted action is that all joined defendants have in some manner brought harm to the plaintiff. (See Note, *supra*, 46 Fordham L.Rev. 963, 985.)

[9]The assertion that each defendant here has engaged in the tortious conduct of producing DES distinguishes our cases from a recent decision of Division Two of this court, *Garcia v. Joseph Vince Co.* (Sept. 15, 1978, 2 Civ. 51614) Cal.App.3d . In that case, the plaintiff was injured in a fencing match by a sabre which was alleged to have been defectively manufactured by one of two fencing equipment suppliers. Because the allegedly defective sabre was either lost or mixed in with other sabres subsequent to the accident, the plaintiff could not establish the identity of the particular supplier who manufactured it. In affirming a judgment of nonsuit, the appellate court, relying on *Wetzel v. Eaton Corporation*, *supra*, 62 F.R.D. 22 (see discussion, *ante*), held that the alternative liability theory of *Summers v. Tice*, *supra*, 33 Cal.2d 80, was inapplicable since the plaintiff could not show, other than by conjecture, which of the two suppliers had violated

(footnote continued on following page)

in her complaint that she is incapable of identifying the particular manufacturer of the DES which caused her harm, her counsel apparently did represent to the court at the hearings on the demurrers that she lacks the knowledge requisite to such an identification.[10] That Sindell is unable to name an individual defendant appears reasonably likely in view of the lapse of time occurring between the use of DES and the manifestation of its allegedly carcinogenic effects, as well as the tracing problems engendered by the treatment of the drug as a fungible product. On remand, however, Sindell should amend her pleadings to indicate with more particularity what her abilities are with respect to the identification of the manufacturer of the DES ingested by her mother. (See *Summers v. Tice*, supra, 33 Cal.2d 80, 88.)

> Assuming that Sindell can amend her complaint to allege lack of knowledge as to which producer of DES caused her injuries, then the doctrine of alternative liability mandates that each defendant here bear the

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a duty to him by manufacturing the defective blade. (*Garcia v. Joseph Vince Co., supra*, at pp. - .)* Before so holding, the court had framed the issue as follows: "[W]here a plaintiff's evidence established that one, but not both, of two defendants produced a defective product, but the evidence does not disclose which one, is that sufficient evidence to permit a jury to determine liability of either defendant?" (*Garcia, supra*, at p. ,** italics added.) Here, in contrast, it is alleged that *each* of the defendants has produced a defective product for the unwary public. Thus, like the hunters in *Summers* who negligently fired their guns, each of the defendant manufacturers of DES is alleged to have engaged in identical, risk-creating conduct.

*Typed opinion pages 6-7.
**Typed opinion page 3.

[10]The court's minute orders sustaining the demurrers of defendants Rexall Drug Company and Eli Lilly and Company on January 24, 1977, and defendants E. R. Squibb & Sons, Inc. and Upjohn Company on March 14, 1977, reflect that Sindell had averred in the proceedings that she cannot name an individual defendant. In fact, Sindell's admission in this regard is referred to in the joint brief filed with this court by Squibb and Upjohn.

> burden of proving its nonresponsibility. The mere fact that there were only two defendants in *Summers* does not, we believe, preclude the principle of law enunciated therein from being applied to the greater number of defendants named here.

Defendants argue that they may be in no better position than the daughters of DES users to identify the manufacturer of the particular DES ingested by their mothers, but the insurmountable difficulties faced by the hunters in *Summers* in showing which one of them actually shot the plaintiff did not deter our Supreme Court in

> . . . that case from shifting the burden of proof on the issue of causation; in practical effect, the court's holding necessarily resulted in joint liability. (4 Witkin, Summary of Cal. Law, *supra*, Torts, § 625, p. 2907.)

We additionally note in this regard that the court in *Summers* found that the case of *Ybarra v. Spangard* (1944) 25 Cal.2d 486 presented "a quite analogous situation . . . ." (*Summers v. Tice*, *supra*, 33 Cal.2d 80, 86.) in *Ybarra*, the plaintiff awoke from an operation to discover that he had somehow been injured during the course of it. (25 Cal.2d at p. 488.) Since the plaintiff could not identify who or what instrumentalities caused his injuries, the Supreme Court found it appropriate to apply the doctrine of res ipsa loquitur to all hospital personnel involved in the surgery. (25 Cal.2d at pp. 490-493.) By thus allowing an inference of negligence to be raised as to all defendants, the court in *Ybarra* may actually have shifted the burden of proof to an entirely innocent, non-negligent party. Here, shifting the burden of proof would be less onerous since it is alleged that each defendant did, in fact, engage in the tortious conduct of producing and marketing DES.

The policy considerations expressed in *Summers* and *Ybarra* are apparent in another case from our Supreme

Court, *Haft v. Lone Palm Hotels, supra*, 3 Cal.3d 756. In that case, plaintiff-survivors sued for the wrongful death of two members of the Haft family who drowned in defendants' unattended motel pool. The defendants' unlawful failure to provide a lifeguard resulted in the plaintiffs' inability to establish the proximate cause of the drownings. (*Id.* at p. 771.) Finding that "[t]he relative culpability of the parties and the burden facing plaintiffs" to be "comparable to the circumstances disclosed in *Summers* and *Ybarra*," the court held that "considerations of 'policy and justice,' . . . shift the burden to 'defendants to absolve [themselves] if [they] can.' [Citation.]" (*Haft v. Lone Palm Hotel, supra*, 3 Cal.3d at p. 773, brackets in original.) In so holding, the *Haft* court drew additional support from cases wherein "several negligent automobile drivers, not acting in concert, successively collide with a plaintiff's person or his property, and the resulting damage is not capable of apportionment"; the court noted that under such circumstances, "the burden 'shifts to *any defendant who might have contributed to the injuries* to prove his own *innocence* or limited liability by showing that such injuries or some particular injury did not result from his negligent conduct.' " (*Haft supra*, at p. 774, italics in original.)

In the recent case of *Dimond v. Caterpillar Tractor Co.* (1976) 65 Cal.App.3d 173, 183, the appellate court referred to *Summers, Ybarra*, and *Haft* in noting that "the law has stood ready to come to the aid of a hapless plaintiff who, through no fault of his own, is unable to provide direct evidence that defendant's breach of duty was a proximate cause of his injuries." The court affirmed that the solution adopted in those cases is a shift in the burden of proof on the issue of causation to the defendant. (*Ibid.*)

Furthermore, the California courts have long recognized the policy objectives of insuring that the costs of injuries

resulting from defective products be borne by the manufacturers that put such products on the market rather than by injured persons who are powerless to protect themselves. (*Ray v. Alad Corp.* (1977) 19 Cal.3d 22, 30; *Greenman v. Yuba Power Products, Inc.* (1963) 59 Cal.2d 57, 63.) The risk of injury can generally be insured by the manufacturer and distributed among the public as a cost of doing business. (*Seeley v. White Motor Co.* (1965) 63 Cal.2d 9, 18-19.) One commentator has noted that the twin goals of accident reduction and risk distribution, first urged by Justice Traynor in his classic concurring opinion in *Escola v. Coca Cola Bottling Co.* (1944) 24 Cal.2d 453, 462, "have replaced a perceived need to insulate business enterprise from tort liability." (Ursin, *Strict Liability for Defective Business Premises — One Step Beyond* Rowland *and* Greenman (1975) 22 UCLA L.Rev. 820, 824, 846.)

We additionally note that the alternative liability doctrine has been incorporated in Restatement Second of Torts section 433B, subsection (3), wherein it is stated: "Where the conduct of two or more actors is tortious, and it is proved that harm has been caused to the plaintiff by only one of them, but there is uncertainty as to which one has caused it, the burden is upon each such actor to prove that he has not caused the harm." The rationale for this rule is stated to be "the injustice of permitting proved wrongdoers, who among them have inflicted an injury upon the entirely innocent plaintiff, to escape liability merely because the nature of their conduct and resulting harm has made it difficult or impossible to prove which of them has caused the harm." (Rest., 2d Torts, *supra*, § 433B, com. f, at p. 446.)

Absent a contrary statute or decision in this state, the Restatements are accorded the status of persuasive authority. (See *Canfield v. Security-First Nat. Bank* (1939) 13 Cal.2d

1, 30-31; *Standard Oil Co. v. Oil, Chemical etc. Internat. Union* (1972) 23 Cal.App.3d 585, 589.)

Defendants maintain that subsection (3) of section 433B should not be applied here since not all manufacturers of DES are before the court. One of the comments to that subsection does indicate that thus far all actors have been joined as defendants in cases in which the subsection has been found applicable, and further recognizes that cases may arise where adjustments to the rule might be necessary because of the complications involved in joining all defendants, such as those resulting from the effect of time lapses. (Rest., 2d Torts, *supra*, § 433B, com. h, at p. 446.) We, however, like the Restatement, do not purport to deal with all the possible problems which may arise from the application of the alternative liability doctrine to the situation before us; the difficulties to be faced at trial are no doubt great. We hold only that at this pleading stage of the litigation we see no logical impediment to the application of that doctrine. Moreover, defendants have ignored the possibility of bringing in other DES manufacturers as cross-defendants pursuant to Code of Civil Procedure section 428.10, subdivision (b). (See *American Motorcycle Assn. v. Superior Court* (1978) 20 Cal.3d 578, 604-607.)

Other Possible Grounds for
the Sustaining of These Demurrers

Several of the defendants assert that even if their demurrers were improperly sustained on the ground of plaintiffs' failure to specify an individual defendant, the rulings of the courts below should nevertheless be upheld by reference to the other grounds stated in the demurrers.

While we are cognizant that a reviewing court is not limited to the reasons specified by the trial court when it is asked to determine whether a general demurrer was prop-

erly sustained (*Altman v. Morris Plan Co.* (1976) 58 Cal.App.3d 951, 962; *Sackett v. Wyatt* (1973) 32 Cal.App.3d 592, 598, fn. 2), we conclude that it would be inappropriate at this time to attempt to deal with all of the alleged insufficiencies in the pleadings before us. A review of the documents related to the demurrers reveals that the question regarding the necessity of specifying which defendant manufactured the DES ingested by each plaintiff's mother has been so pervasive in the proceedings up to this point that it is unlikely the other possible bases for sustaining the demurrers have received the treatment in the trial courts they deserve. The fact that, with one exception, each of the demurrers was sustained without leave to amend reflects the lack of opportunity the parties have had to refine the pleadings at the trial court level. Our holding herein does not, of course, prohibit the respective superior courts from now giving consideration to the other grounds stated in the demurrers should defendants choose to reassert them upon remand.[11]

Expedience, however, mandates that we address at least the limitations question raised by the instant demurrers since

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[11]We note that except for the proximate cause question raised by plaintiffs' failure to identify the manufacturer(s) of the drug taken by their mothers and the possible bar of the statute of limitations, both of which issues are discussed herein, the objections raised by defendants' general demurrers went to individual causes of action, rather than to the complaints as a whole. Defendants also supplemented their general demurrers by interposing numerous special demurrers for uncertainty.

In *Stowe v. Fritzie Hotels, Inc.* (1955) 44 Cal.2d 416, 425, our Supreme Court stated:

> "When a demurrer based upon both general and special grounds is sustained and the order mentions only the general ground, impliedly the ruling was made either without consideration of the special grounds or upon a determination that they are not well taken. If the general demurrer was sustained erroneously, the trial judge should be directed to consider the special grounds." (See also *Briscoe v. Reader's Digest Assoc., Inc.* (1971) 4 Cal.3d 529, 544.)

a determination adverse to plaintiffs on that issue would completely dispose of these cases. We note preliminarily in this regard that the demurrers would only be sustainable on the ground of the bar of the statute of limitations if the faces of the complaints *affirmatively* disclose facts showing the availability of that defense. (*Valvo v. University of Southern California* (1977) 67 Cal.App.3d 887, 895; 3 Witkin, Cal. Procedure (2d ed. 1971) Pleading, § 797, p. 2410.)

Defendants' limitations argument is premised on the assumption that the applicable period is governed by Civil Code section 29, which provides:

> "A child conceived, but not yet born, is to be deemed an existing person, so far as may be necessary for its interests in the event of its subsequent birth; but any action by or on behalf of a minor for personal injuries sustained prior to or in the course of his birth must be brought within six years from the date of the minor, and the time such minor is under any disability mentioned in Section 352 of the Code of Civil Procedure shall not be excluded in computing the time limited for the commencement of the action."

That section, however, appears not to be directed toward situations like those before us, namely, where the tortious conduct occurred prior to birth but the injury did not manifest itself until long after infancy.[12] (Cf. *G. D. Searle & Co. v. Superior Court* (1975) 49 Cal.App.3d 22, 25.)

In view of the unusual circumstances present here, we conclude that these actions are governed by the one-year limitations period prescribed in Code of Civil Procedure section 340, subdivision 3, which, in cases involving injury

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[12]It is alleged in both complaints that the cancer caused by DES exposure is believed to strike after a minimum latent period of ten to twelve years.

from drug ingestion, does not begin to run until the time the plaintiff discovers or in the exercise of reasonable care should have discovered that he or she has been damaged by the defendant's product. (*Warrington v. Charles Pfizer & Co.* (1969) 274 Cal.App.2d 564, 566-567.)

Turning to the pleadings before us, we note that Rogers appears to have filed her original action on July 15, 1976. In her first amended complaint, filed December 17, 1976, it is alleged that in August of 1975 Rogers' mother received a letter from the Chicago Lying-In Hospital, dated July 15, 1975,[13] indicating that the hospital was conducting tests to determine a possible link between DES and abnormalities in the offspring of women who were prescribed the drug during their pregnancies. Thereafter, in October 1975, Rogers was examined and found to have cervical cancer. She further alleges that "Prior to this time plaintiff was completely unaware of this condition, having experienced no noticable [*sic*] symptoms and having been advised of no abnormal growths in any of her previous annual gynocological [*sic*] examinations." Rogers' age is not stated in her pleadings. Under these alleged facts, it is clear that Rogers' original complaint was filed within one year of the earliest reasonable opportunity she had to discover that she may have been injured by exposure to DES.

Sindell's complaint was filed on August 2, 1976. It alleges that Sindell was alerted "in the past year by newspaper reports" of the possible connection between DES and the development of cancerous and precancerous growths in women exposed to the drug before birth. It is further alleged that a subsequent gynecological examination revealed that

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[13]Rogers' first amended complaint actually states that the hospital's letter was dated July 15, 1976, an obvious typographical error.

Sindell had developed vaginal and cervical adenosis and that she thereafter suffered surgery in May 1976 for the removal of a cancerous bladder tumor. Sindell's age is not alleged. While her complaint is less than a model pleading in this regard, we conclude that nothing on the face of it affirmatively discloses that Sindell is barred by the one-year limitations period from pursuing her action.

DISPOSITION

The judgments (orders of dismissal) entered in favor of defendants Abbott Laboratories, Eli Lilly and Company, Rexall Drug Company, E. R. Squibb & Sons, Inc., and Upjohn Company in No. 51845 and in favor of defendants Rexall Drug Company, E. R. Squibb & Sons, Inc., and Upjohn Company in No. 51875 are reversed and the causes remanded for further proceedings not inconsistent with the views herein expressed. In No. 51845, the superior court is directed to permit plaintiff Sindell to amend her complaint so as to indicate whether or not she is capable of identifying the particular manufacturer of the DES ingested by her mother.

CERTIFIED FOR PUBLICATION

Klein, *P.J.*

We concur:

Allport, *J.*

Potter, *J.*

APPENDIX C.

Judgment.

In the Supreme Court of the State of California.

Judith Sindell, Plaintiff and Appellant, vs. Abbott Laboratories et al., Defendants and Respondents. L.A. No. 31063. Appeal County Los Angeles, Superior Court No. 169127.

Entered March 20, 1980.

The above-entitled cause having been heretofore fully argued, and submitted,

It Is Ordered, Adjudged, and Decreed by the Court that the Judgment of the Superior Court of the County of Los Angeles in the above-entitled cause, is hereby Reversed. Appellant is to recover costs on appeal.

APPENDIX D.

Judgment.

In the Supreme Court of the State of California.

Maureen Rogers, Plaintiff and Appellant, vs. Rexall Drug Company et al., Defendants and Respondents. L.A. No. 31063. Appeal County Ventura, Superior Court No. 61220.

Entered March 20, 1980.

The above-entitled cause having been heretofore fully argued, and submitted,

It Is Ordered, Adjudged, and Decreed by the Court that the Judgment of the Superior Court of the County of Ventura in the above-entitled cause, is hereby Reversed. Appellant is to recover costs on appeal.

APPENDIX E.

PETITION FOR REHEARING.

In the Supreme Court of the State of California.

IN THE SUPREME COURT OF THE STATE OF CALIFORNIA.

Judith Sindell, *Plaintiff and Appellant*, *vs.* Abbott Laboratories, Eli Lilly and Company, Rexall Drug Company, E.R. Squibb and Sons, Inc., and the Upjohn Company, *Defendants and Respondents*. Maureen Rogers, *Plaintiff and Appellant*, *vs.* Rexall Drug Company, E.R. Squibb & Sons, Inc., and the Upjohn Company, *Defendants and Respondents*.

To the Honorable Justices of the Supreme Court of the State of California:

Defendants and Respondents, E.R. Squibb & Sons and The Upjohn Company, respectfully petition for a rehearing of the above cases. The court's opinion filed March 20, 1980, considers legal questions of great importance. It is submitted that the matter should be reheard for the following reasons:

I.

A Change in the Law of This Magnitude Should Remain the Province of the Legislature, Not the Judiciary.

As the Court frankly observed in its opinion, until the present moment the plaintiffs in these cases stated no cause of action under established law (Typed Opinion at 29.). Neither the doctrine of "alternative liability," that of "concert of action" and "civil conspiracy," nor that of "enterprise liability" supports the plaintiffs' right to recover.

Instead, the present lawsuits survive the pleading stage only through the court's creation of a new rule of law. The effect of such rule, if permitted to stand, cannot now be estimated. At the least, it would transform whole areas of tort law, creating liability where there now is none, isolating

California on the basis of newly-multiplied costs of distributing products, and burdening consumers with the added costs of sending products into a state levying unanticipatable liabilities.

It is submitted that this case, most particularly at its pleading stage, provides insufficient data upon which to base such a drastic change of law. What the costs might be, and whether society is willing to shoulder them, are uniquely matters of fact-finding and policymaking within the sole capability of the Legislature. Until such fact-finding is accomplished, the wisdom of the economic reshaping mandated by this decision can only be guessed at.

This court has recognized it is the legislative function to change rules of law that long have been uniformly construed, such revision coming only after "a complete examination of all of the consequences," *Estate of Calhoun*, 44 Cal.2d 378, 387 (1955); *see Gombos v. Ashe*, 158 Cal.App.2d 517, 528 (1958). The new rule suggested in the court's opinion is just such type of lawmaking. This kind of answer to asserted societal needs should be the result only of the legislative process.

II.

The Judgment of This Court Represents State Action Subject to the Limitations of the Fourteenth Amendment of the Federal Constitution.

By now, there is no doubt that decisions of this court are subject to the restrictions of the Fourteenth Amendment insofar as they affect protected constitutional rights. *Saunders v. Shaw*, 244 U.S. 317 (1917); *Home Telephone and Telegraph Co. v. City of Los Angeles*, 227 U.S. 278 (1912); *Ex parte Virginia*, 100 U.S. 339 (1879).

As stated by the United States Supreme Court in *Chicago, Burlington & Quincy Railroad Co. v. Chicago*, 166 U.S. 225 (1897):

As stated by the United States Supreme Court in *Chicago, Burlington & Quincy Railroad Co. v. Chicago,* 166 U.S. 225 (1897):

> "[T]he prohibitions of the [Fourteenth] Amendment refer to all the instrumentalities of the State, to its legislative, executive and judicial authorities, and, therefore, whoever by virtue of public position under a state government deprives another of any right protected by that amendment against deprivation by the state, 'violates the constitutional inhibition . . .' " 166 at 233-234.

Thus, the Court said, a judgment of the highest court of a state that conflicts with the Constitution would contravene the Fourteenth Amendment.

More recently, the rule was restated in these terms:

> "There can now be no doubt that the application by the judiciary of the state's common law, even in a lawsuit between private parties, may constitute state action which must conform to the constitutional strictures which constrain the government," *Edwards v. Habib,* 397 F.2d 687, 691 (D.C. Cir. 1968), *cert. den.,* 393 U.S. 1016 (1969),

As applicable to the present case, the federal high court has held that affirmance of a civil damage award, even one arriving in the procedural garb of a demurrer, can constitute a deprivation of federally protected rights. For example, in *New York Times Co. v. Sullivan,* 376 U.S. 254 (1964), the Supreme Court of Alabama affirmed a civil judgment against the defendant publisher. Granting review, the U.S. Supreme Court declared that the state rule of law applied by the Alabama Court contravened the Fourteenth Amendment. Said the Court:

> "Although this is a civil lawsuit between private parties, the Alabama courts have applied a state rule of

> law which petitioners claim to impose invalid restrictions on their constitutional freedoms of speech and press. It matters not that that law has been applied in a civil action and that it is common law only, though supplemented by statute." 376 U.S. at 265.

Likewise, the high court applied the same principle to the affirmance by the California Court of Appeal of the sustaining of a demurrer in a civil action, *Barrows v. Jackson,* 346 U.S. 249 (1953). In that case, the U.S. Supreme Court affirmed the judgment of the California court. However, the Supreme Court noted that the state court's decision, even though involving a demurrer in a civil action, still was subject to the limitations of the Fourteenth Amendment. Had the state decision gone the other way, the Supreme Court said, the judgment would have been reversible on Fourteenth Amendment grounds. 346 U.S. at 254.

The similarity of *New York Times* and *Barrows* to the present action demonstrates that whether or not the opinion of this court is valid under state common law rules, those rules cannot be applied in a manner infringing Fourteenth Amendment protections.

That fact, of course, was recognized during the pendency of this action in this court, both in the argument of the parties (see Petition for Hearing of E. R. Squibb & Sons, Inc., at 27-30), and in the opinion of the court itself. (See Typed Opinion at 17, footnote 17).

III.

This Court's Judgment Contravenes the Due Process Clause of the Fourteenth Amendment by Establishing an Irrebuttable Presumption of Liability on the Part of the Defendants.

The effect of this court's decision, reduced to essentials, is to create the presumption of fault and liability as to all

defendants fitting a broad description. Thus, liability is levied upon all parties who manufactured DES during a particular time period. Such defendants are irrebuttably presumed to share in the fault for the harm asserted by plaintiffs.

Such irrebuttable presumptions, however, have received a most careful constitutional scrutiny by the U.S. Supreme Court. As that Court explained:

> "[T]he due process clauses of the Fifth and Fourteenth Amendments set limits upon the power of Congress or that of a state legislature to make the proof of one fact or group of facts evidence of the existence of the ultimate fact on which guilt is predicted. . . . Under our decisions, a statutory presumption cannot be sustained if there be no rational connection between the fact proved and the ultimate fact presumed, if the inference of the one from proof of the other is arbitrary because of lack of connection between the two in common experience," *Tot v. United States*, 319 U.S. 463, 467-468 (1943).

The same strict review also is applied to irrebuttable presumptions created judicially. *Ray v. Folsom*, 166 F.Supp. 390, 395 (W.D. Ark. 1958).

Thus, in *Vlandis v. Kline*, 412 U.S. 441 (1973), the Supreme Court critically viewed a Connecticut statute providing that out-of-state persons who entered the state university as freshmen could not during their four years of college qualify for the lower tuition rate charged residents. Such statute, the high court held, created an irrebuttable presumption of nonresidence. The court struck down the statute as violating the Due Process Clause of the Fourteenth Amendment in that the presumption was not necessarily or universally true as to all individuals subject to its rule.

Similarly, in *Cleveland Board of Education v. LaFleur*, 414 U.S. 632 (1974), the Court faced an irrebuttable presumption involving schoolteachers. The defendant board of

education required all pregnant schoolteachers to take maternity leave five months before the expected childbirth. Once again, the Court held, the rule irrebuttably presumed that every pregnant teacher is unable to fulfill her duties beyond the mandatory leave deadline. Because such presumption is not universally true, the Court held the rule violates the Due Process Clause of the Fourteenth Amendment.

Numerous other cases also have struck down on constitutional grounds irrebuttable presumptions that obviously were not universally correct as to all members of the disabled class. *See, e.g., United States Department of Agriculture v. Murry*, 413 U.S. 546 (1973); *Stanley v. Illinois*, 405 U.S. 645; *Bell v. Burson*, 402 U.S. 535; *Morrison v. California*, 291 U.S. 82 (1933); *Bandini Petroleum Co. v. Superior Court*, 284 U.S. 8 (1931); *Bailey v. Alabama*, 219 U.S. 219 (1911); *Seaboard Air Line R. Co. v. Bailey*, 190 F.2d 812 (5th Cir. 1951); *Minski v. United States*, 131 F.2d 614 (6th Cir. 1942) *aff'd* 319 U.S. 463.

In much the same way, the Supreme Court also has struck down on due process grounds unfair shifts in the burden of proof, including, for example, those requiring a party to prove a negative to avoid liability. See *Speiser v. Randall*, 357 U.S. 513 (1958); *First Unitarian Church of Los Angeles v. County of Los Angeles*, 357 U.S. 545 (1958).

The rule established by the above decisions applies to the present case. The effect of this court's decision is to create an irrebuttable presumption that each defendant manufacturer contributed to harm assertedly suffered by the plaintiffs. Obviously such is not correct, and as to each plaintiff all except one or two defendants lack any connection whatsoever with their alleged injury. However, just as in the federal cases cited above, there is no means by which the present defendants can rebut such a presumption.

As a result, whether viewed as a shift of the burden of proof or as creating a presumption, the rule established in this court's decision applies a conclusive, irrebuttable presumption in this and every other case utilizing the court's new rule.

The imposition of such presumptions has been held to violate the Fourteenth Amendment in cases similar to the present one. In *Western & A.R.R. v. Henderson*, 279 U.S. 639 (1929), the Court considered a Georgia statute providing railroads are liable for all damage occurring in connection with their equipment, unless the railroad can prove its freedom from fault. Said the Court:

> "The mere fact of collision between a railway train and a vehicle at a highway grade crossing furnishes no basis for any inference as to whether the accident was caused by negligence of the railway company, or of the traveler on the highway or of both, or without fault of any one." 279 U.S. at 642-643.

Because of that, the Court held, the statute violated the Due Process Clause of the Fourteenth Amendment as being unreasonable and arbitrary.

In the same way, in *Manley v. State of Georgia*, 279 U.S. 1 (1929), the court reviewed another Georgia statute providing every bank insolvency was to be prima facie proof of fraud by the bank's president and directors. Once again, the court held the presumption irrational and, therefore, unconstitutional. The court noted under the statute the size of bank was irrelevant, and fraud would be imputed to all officers, whether the bank had three or as many as 25, *See also McFarland v. American Sugar Refining Co.*, 241 U.S. 79 (1916) (unconstitutional to presume participation in a monopoly by the fact of selling sugar at a certain price).

The presumption created by this court's decision falls within the class of those reviewed above. It is submitted

that the automatic presumption of liability imposed against all defendants in this case violates the Due Process Clause of the Fourteenth Amendment.

IV.

This Court's Judgment Contravenes the Due Process Clause of the Fourteenth Amendment by Creating Liability Without Proof of Fault.

One effect of this court's decision is to impose liability upon a particular defendant without proof the defendant committed any wrongdoing. However, such rule would contravene constitutional guarantees that liability cannot be imposed without evidence supporting an accusation. Thus, in cases where liability or guilt was imposed without evidentiary support, the U.S. Supreme Court has reversed, holding such judgments in violation of the Fourteenth Amendment *See, e.g., Thompson v. City of Louisville*, 362 U.S. 199 (1960); *Schware v. Board of Bar Examiners of the State of New Mexico*, 353 U.S. 232 (1957); *Bell Telephone Co. v. Pennsylvania Public Utility Comm'n*. 309 U.S. 30 (1940).

Facts relevant to the present case are found in *Dachon v. New Hampshire*, 414 U.S. 478 (1974). In that case, a teenage girl purchased a button bearing an objectionable slogan from a shop operated by the defendant. As a result, the operator was convicted of contributing to the delinquency of a minor. On review, the U.S. Supreme Court held an essential element of evidence was missing—there had been no proof the operator himself personally sold the button to the teenager. Without such evidence, the Court held, the defendant's mere status as operator of the shop was insufficient to connect him with the harm allegedly done to the minor. Therefore, the Court held the operator's conviction violated his due process rights.

The constitutional requirement of evidence supporting liability or guilt also means that a defendant cannot be assigned the task of proving his or her own innocence. As the federal high court held in *Norwood v. Harrison*, 413 U.S. 455 (1973):

> "No presumptions flow from mere allegations: no one can be required, consistent with due process, to prove the absence of violation of law." 413 U.S. at 471.

In the present case, it is uncontroverted that plaintiffs have no evidence demonstrating the liability of any individual defendant. In such case, the imposition of liability in the absence of supporting evidence amounts to a deprivation of due process.

V.

This Court's Judgment Contravenes the Due Process Clause of the Fourteenth Amendment by Creating Liability Even Where a Plaintiff Cannot Establish All Necessary Elements of Her Cause of Action.

A further consequence of this court's decision is that liability is to be imposed even upon defendants not the causative agent of the asserted harm. This is so because the changes are small that any typical defendant in the present case actually caused the injury complained of.

To nevertheless impose liability upon all such defendants effectively eliminates the requirement of proving actual causation in tort actions. As a consequence, plaintiffs who succeed in fitting their causes of action into this court's new rule are spared the necessity of establishing the element of causation, unlike all other tort claimants. Conversely, defendants subjected to lawsuits employing this new rule are denied the safeguard afforded by the causation requirement—that is, they well may be held liable for injuries they never caused.

Such a revision in long-established tort principles, however, cannot be made in a vacuum. Eliminating the causation requirement reduces the evidentiary protection afforded defendants, a protection of constitutional significance. For example, in *Ocala Star-Banner Co. v. Damron*, 401 U.S. 295 (1971), a state court permitted a public official to recover libel damages without proof the assertedly damaging publication was made with "actual malice." Such recovery, however, had the effect of eliminating the established requirement that malice be shown. On review, the U.S. Supreme Court reversed the judgment, holding it unconstitutional to impose civil liability without proof of all necessary elements of the cause of action.

Because permitting recovery in the present case without proof of causation would have the same effect, it is submitted that the federal Constitution prohibits imposition of liability without proof of each element of the product liability cause of action.

VI.

This Court's Judgment Contravenes the Equal Protection Clause of the Fourteenth Amendment by Creating Differing Liability Standards Among Similarly-Situated Enterprises.

It can be seen at once that the decision of this court will have only selective applicability among tort defendants. The rule it establishes can be applied only to defendants who are part of a multi-firm industry manufacturing fungible products. Defendants belonging to businesses or industries having different internal structures will not face liability under the court's decision.

Such haphazard applicability means that two standards of liability are established: one for industries having the characteristics of the present pharmaceutical manufacturers,

another for all other product-liability defendants. It can be seen at once such distinction has no basis in logic, for the propensity of a product to injure, or the problems involved in assuring its safety, bear no rational connection to the internal structure of the industry producing it. Thus, two firms choosing to do business in California may face differing liability standards having no connection to the products they sell. One—similar to the present defendants—will face unlimited liability without proof of fault, while the second will incur only liability actually proven to be its responsibility.

This type of disparate treatment of similarly situated parties, however, cannot be maintained under the limitations of the Equal Protection Clause of the Fourteenth Amendment. That provision denies states the power to treat similarly-situated persons in different ways. *Reed v. Reed,* 404 U.S. 71 (1971); *Graham v. Richardson,* 403 U.S. 365 (1971).

These equal protection requirements apply with full strength to the liability of business enterprises. In *Connolly v. Union Sewer Pipe Co.*, 184 U.S. 540 (1902), the U.S. Supreme Court considered an Illinois anti-trust statute applying to all businesses but expressly exempting producers of agricultural products or livestock. Striking down the statute on Fourteenth Amendment grounds, the high court held the law "is not a legitimate exertion of the power of classification, rests upon no reasonable basis, is purely arbitrary, and plainly denies the equal protection of the laws to those against whom it discriminates," 184 U.S. at 563.

Likewise, in *Smith v. Cahoon,* 283 U.S. 553 (1931), the Court again held unconstitutional a state classification providing different treatment for closely similar businesses. The statute required motor carriers to obtain certification and insurance, but excepted carriers of certain commodities.

Because the classification had no relation to the purpose of the statute, the Court held it "constituted a violation on the appellant's constitutional rights." 283 U.S. at 587. In the same way, a district court following the principles established by the Supreme Court held it was unconstitutional to permit punitive damages in personal injury and property damage cases, yet deny them in wrongful death cases. *In re Paris Air Crash of March 3, 1974*, 427 F.Supp. 701 (C.D.Cal. 1977). Other cases establishing the same rule are *Power Manufacturing Co. v. Saunders*, 274 U.S. 490 (1927); and *Truax v. Corrigan*, 257 U.S. 312 (1921).

It is submitted that the distinction among defendants established by this court's decision lacks a rational basis and, therefore, creates a classification violating equal protection guarantees of the federal Constitution.

VII.

This Court's Judgment Contravenes the Equal Protection Clause of the Fourteenth Amendment by Creating a Rule of Liability Based on Defendants' Economic Status.

In reaching its decision, this court found that no existing rule of liability supported the position of the present plaintiffs. Yet, it held a new rule of liability may be imposed based in part on the fact defendants are better able to bear the cost of injury than the plaintiffs. (Typed Opinion at 30.).

To the extent the decision imposes liability upon defendants because of their economic status, however, serious constitutional questions are raised. It is settled that in applying its laws, a state's drawing lines on the basis of wealth renders such classification highly suspect and warrants exacting judicial scrutiny. *McDonald v. Board of Election Comm'rs of Chicago*, 394 U.S. 802, 807 (1969).

The constitutional question raised is whether California has a compelling interest in assessing liability against the present defendants based upon their economic status. Numerous decisions of the U.S. Supreme Court have found that an individual's wealth provides no reasonable basis for treating that individual differently than others. *See, e.g., Boddie v. Connecticut*, 401 U.S. 371 (1971); *Harper v. Virginia State Board of Elections*, 383 U.S. 663 (1966); *Douglas v. People of State of California*, 372 U.S. 353 (1963); *Smith v. Bennett*, 365 U.S. 708 (1961).

The Supreme Court once stated the above proposition in these words:

> "There can be no equal justice where the kind of trial a man gets depends on the amount of money he has." *Griffin v. People of the State of Illinois*, 351 U.S. 12, 19 (1956)

Because liability is being imposed on the present defendants because of their supposed wealth, it is submitted that the new rule established by this court is inconsistent with the equal application of justice required by the federal constitution.

VIII.

This Court's Judgment Contravenes the Due Process Clause of the Fourteenth Amendment by Creating Liability Based Solely on Defendants' Status as Pharmaceutical Manufacturers.

A key distinction between the new rule established in this case and that used in all prior cases is the ultimate basis for liability. Under principles used heretofore, liability accrued because of something a defendant did or did not do. Under that established rule, as this court acknowledges, the present defendants have not incurred liability because no evidence connected their conduct with plaintiffs' asserted injuries.

To remedy that perceived failing, this court's answer is to create a form of liability based not on conduct but upon status. Under the rule established by the majority, liability attaches to whomever fits the key description: one occupying the role of manufacturer during a specified period. Thus, it can be seen that liability is based upon a defendant's status, rather than conduct.

"Status" liability, however, has fared poorly when subjected to constitutional scrutiny. For example, in *Robinson v. State of California*, 370 U.S. 660 (1962), the defendant was convicted under a statute making it illegal to be addicted to the use of narcotics. Reversing the conviction, the U.S. Supreme Court held such a standard of liability violates the Fourteenth Amendment. The Court particularly gave attention to the distinction between liability for one's conduct as opposed to one's status. *See* 370 U.S. at 666.

The same constitutional principle applies here. Establishing "status liability" ignores the determination that is at the heart of tort law: whether the defendant did an act or failed to do an act, thereby causing harm to another. To create liability without such determination is inconsistent with the guarantees of the Fourteenth Amendment.

IX.

This Court's Judgment Contravenes the Commerce Clause of the Federal Constitution by Creating an Invalid Burden on Interstate Commerce.

Because pharmaceutical products, such as those produced by the defendants, are distributed to a national market, the validity of this court's decision also must be tested under the Commerce Clause of the federal Constitution. The purpose underlying enactment of that clause, of course, was to break down state-erected barriers to commerce so as to ensure a national marketplace.

Thus, under the Commerce Clause "no state has power to make any law or regulation which will affect the free and unrestrained intercourse and trade between the states . . . ." *Pittsburgh & S. Co. v. Bates*, 156 U.S. 577, 585 (1895); *see Dahnke-Walker Milling Co. v. Bondurant*, 257 U.S. 282 (1921). The prohibition against erecting trade barriers applies to all state-imposed rules, whether or not they discriminate between products made locally and those arriving through interstate commerce. Robbins v. Taxing District of Shelby County, 120 U.S. 489 (1887); *State of Minnesota v. Barber*, 136 U.S. 313 (1890); *Brimmer v. Rebman*, 138 U.S. 78 (1891).

The new rule of liability created by this court's decision does burden interstate commerce in at least four ways. First, the decision will raise the overall cost of products whose manufacturers are subject to the increased liabilities now to be imposed. In simple logic, the increased cost of doing business occasioned by this new liability must be added to the cost of the products affected. This simple fact of increased cost of products itself amounts to a burden on interstate commerce. For example, in *Bibb v. Navajo Freight Lines, Inc.*, 359 U.S. 520 (1959), the U.S. Supreme Court dealt with an Illinois statute requiring trucks traveling through that state to use a distinctive type of mudguard. The high court held the cost of complying with Illinois' unique rule was one factor making such rule unconstitutional under the Commerce Clause. *See also Raymond Motor Transportation, Inc. v. Rice*, 434 U.S. 429 (1978); *Soap and Detergent Assn. v. City of Chicago*, 357 F.Supp. 44 (N.D. Ill. 1973), *rev'd on other grounds*, 509 F.2d 69 (7th Cir.), *cert. den.*, 421 U.S. 1978 (1975). Furthermore, such cost increases will not be limited only to California, for manufacturers may not discriminate in price among the various states. Therefore, this court's decision will require the

spreading of the resultant price increases among all states, not merely California.

Second, the burden of additional, unpredictable liability in certain pharmaceutical products—notably the newer ones—will encourage manufacturers to avoid economic risks by emphasizing the distribution of older, established pharmaceuticals. The effect of such policy will be to decrease the variety of pharmaceuticals available, particularly those more recently developed. This court's decision, therefore, will adversely affect the development of new pharmaceutical products, and that burden will be felt nationally.

Third, to the extent the present decision raises prices and decreases the availability of certain pharmaceuticals, it may cause a decrease in the volume of pharmaceutical sales. Such an adverse impact upon the volume of interstate commerce itself amounts to a burden upon commerce inconsistent with the Commerce Clause. *Great Western United Corp. v. Kidwell*, 577 F.2d 1256 (5th Cir. 1978).

Fourth, the increased level of liability in the distribution of pharmaceuticals will increase the cost of doing business in that field. Such increased costs will make it more difficult and expensive for new or outside firms to enter the pharmaceutical field. Such a raising of barriers to entry once again imposes a burden upon interstate commerce. *See United States v. Aluminum Co. of American*, 148 F.2d 416 (2d Cir. 1945); *Philadelphia World Hockey Club, Inc. v. Philadelphia Hockey Club, Inc.*, 351 F.Supp. 462 (E.D. Pa. 1972; *United States v. United Shoe Machinery Corp.*, 110 F.Supp. 295 (D.Mass. 1953), *aff'd*, 347 U.S. 521 (1954). For that reason, this court's decision also is inconsistent with the Commerce Clause.

In assessing the constitutionality of a state's regulation of interstate commerce, it should be noted that strong state justification is required. The traditional "rational relation-

ship'' test applied to due process cases does not apply to state-imposed burdens upon interstate commerce. *Great Western United Corp. v. Kidwell, supra,* 577 F.2d at 1285. It is submitted that whatever reasons support this new rule, they provide insufficient justification for the burden that is imposed upon commerce.

X.

This Court's Judgment Contravenes the Commerce Clause of the Federal Constitution by Burdening Interstate Commerce Without Resort to Less Burdensome Alternatives.

Even when a state can justify its establishing rules that burden interstate commerce, such rules still are invalid if less burdensome alternatives exist. *Great Atlantic & Pacific Tea Co., Inc. v. Cottrell,* 424 U.S. 366 (1976); *Pike v. Bruce Church, Inc.,* 397 U.S. 137 (1970).

The court's opinion in the present case gives no indication that alternatives were sought or considered imposing a lighter burden on interstate commerce than the one chosen. Yet, because of the sweeping form of liability imposed by this court, there appears to be a duty first to weigh methods of achieving the court's purpose while minimizing the effect upon the free flow of products.

To the extent the present decision fails to review and consider alternatives, its result contravenes the Commerce Clause.

Conclusion.

On the basis of the foregoing argument and authorities, defendants and respondents, E. R. Squibb & Sons and The Upjohn Company, submit that a rehearing of this matter is necessary to resolve important federal constitutional questions.

Respectfully submitted,

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APPENDIX F.

Order of the California Supreme Court Denying Rehearing.

Sindell v. Abbott Laboratories/Rogers v. Rexall Drug Company, et al. L.A. 31063 (26 Cal.3d 588). May 7, 1980. Tobriner, J., did not participate.

White, J., sitting under assignment of the Chairperson of the Judicial Council.

Respondent's petitions for rehearing denied.

Clark, J., Richardson, J., and Manuel, J., are of the opinion that the petitions should be granted.

APPENDIX G.

Excerpt from Petition for Hearing in the California Supreme Court.

[Explanatory note: The following is an excerpt from the Petition for Hearing filed in the California Supreme Court by E. R. Squibb & Sons, Inc., on October 31, 1978. Pursuant to Rule 28(d) (3) of the *California Rules of Court*, The Upjohn Company adopted this portion of Squibb's Petition for Hearing. The petitions for hearing of all defendants were granted by the California Supreme Court on December 13, 1978. However, the constitutional issues arising from the decision of the California Supreme Court, which are the subject of this certiorari petition, are very different from those arising from the decision of the Court of Appeal. In any event, this excerpt is included in the Appendix in order to show the first appearance of constitutional issues in this litigation].

It is the position of respondent E. R. Squibb & Sons, Inc., that any judicially established rule allowing a plaintiff to recover against one or more manufacturers without product identification and tracing would be unconstitutional. In particular, the defendants would be denied equal protection of the laws and would be deprived of property without due process of law, in violation of Fourteenth Amendment to the United States Constitution, and corresponding portions of the Constitution of the State of California. [Article I, Sections 11 and 21.]

The drug industry would be denied equal protection of the laws because a rule dispensing with proof of cause in fact would be applicable to them, although not applicable in all tort cases. The defendants would be deprived of due process of law, because, in effect, an unwarranted legal presumption would have been established.

That the rule proposed by plaintiffs and appellants would be etablished by judicial decision, rather than by legislative action, does not affect its possible constitutionality. Judicial decisions by state courts, as well as legislative enactments, are subject to the restraints of substantive due process. See *American Ry. Express v. Kentucky*, 272 U.S. 269 (1927); *Prudential Ins. Co. v. Cheek*, 259 U.S. 530 (1922); *Patterson v. Colorado*, 205 U.S. 454 (1907); *Backus v. Port St. Union Depot Co.*, 169 U.S. 557 (1898); *Chicago, B. & O. R.R. v. Chicago*, 166 U.S. 226 (1897). If plaintiffs' theories are adopted by this court as a basis for tort liability, such a holding will violate the Fourteenth Amendment. It will result in taking the property of all the defendants to pay for harm which may have been caused by the product of only one defendant—or very probably by a supplier not even a party to this lawsuit—and over whom the defendants had no control and with whom they had no meaningful contact or relationship.

The general tests for applying the principle of equal protection are set forth in many cases. See, for example, *Serrano v. Priest*, 5 Cal.3d 584 (1971) and the various federal and state court decisons cited therein. Equal protection and due process of law are violated "if a party is denied the right to have his cause tried and determined in accordance with the procedures that are applied in *other cases of like character*." (Emphasis added.) *Collins v. Superior Court*, 145 Cal.App.2d 588, 589 (1956). The words "other cases of like character" would have to refer to other torts actions in which the plaintiff has the burden of proving causation in fact. The inability of some plaintiffs to bear the uniformly established burden of proof does not justify dispensing with that burden in an arbitrarily selected group of cases.

To abandon the requirement of product identification and tracing would, in effect, establish a presumption that

each and every defendant in a case violated a duty to the particular plaintiff, causing injury. Such a presumption would be an unconstitutional departure from the requirements of due process of law. A state may declare a *prima facie* presumption to be the legal effect of proof of certain facts, but the due process clause of the Fourteenth Amendment to the United States Constitution requires that there be a rational connection between the facts proved and the fact presumed. *People v. Wells*, 33 Cal.2d 330, 346 (1949); *Tot v. United States*, 319 U.S. 463, 467 (1943).

It is constitutionally insufficient to argue that without the proposed theories of liability, plaintiffs will be left remediless and that that is inequitable. In *Rees v. Watertown*, 86 U.S. (19 Wall.) 107 (1873), the Supreme Court, relying upon the Magna Carta and the due process clause, stated: "A court of equity cannot, by avowing that there is a right but no remedy known to the law, create a remedy in violation of law, or even without the authority of law." 86 U.S. at 122.

In the cases at bar, the possible inability of plaintiffs to prove their cases cannot be blamed on any conduct of the defendants. Plaintiff Rogers has been able to identify the actual manufacturer involved in her own case. It is possible that plaintiff Sindell might be able to do so after pursuing investigation or discovery. In any event, the Constitution requires proof of cause in fact, before a defendant can be held liable to a plaintiff. To hold otherwise, would be to create a new tort, consisting solely of being a manufacturer of DES. It would represent unconstitutional discrimination of a class of manufacturers, treated in a manner unlike the standards of justice applied to other defendants.

For the foregoing reasons, the Supreme Court of California should not adopt any rule which would allow violation of the constitutional rights of the defendants, depriving them of property in a discriminatory fashion, without due process of law.

Supreme Court, U. S.
FILED
SEP 5 1980
MICHAEL RODAK, JR., CLERK

Nos. 80-157, 80-158,
80-170, 80-172
IN THE

Supreme Court of the United States

October Term, 1980

E. R. SQUIBB & SONS, INC.,
Petitioner,

vs.

JUDITH SINDELL, *et al.*,
Respondents.

THE UPJOHN COMPANY,
Petitioner,

vs.

JUDITH SINDELL, *et al.*,
Respondents.

REXALL DRUG COMPANY and ELI LILLY AND COMPANY,
Petitioners,

vs.

JUDITH SINDELL, *et al.*,
Respondents.

ABBOTT LABORATORIES,
Petitioner,

vs.

JUDITH SINDELL, *et al.*,
Respondents.

BRIEF IN OPPOSITION TO PETITIONS FOR WRITS OF CERTIORARI.

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QUESTIONS PRESENTED.

This case presents the following federal constitutional questions:

1. Whether Petitioners waived their rights to assert certain constitutional issues by failing to properly raise the issues in the courts below.

2. Whether a judicial modification of the doctrine of *Summers v. Tice*, 33 Cal.2d 80 (1948), which apportions damages in proportion to market share, violates the Due Process and Equal Protection Clauses of the Fourteenth Amendment.

3. Whether a judicial modification of the doctrine of *Summers v. Tice*, which apportions damages in proportion to market share, is prohibited under the Supremacy Clause or is invalid as an impermissible burden on interstate commerce.

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STATEMENT OF CASE.

A. Introduction.

In *Sindell*, the California Supreme Court modified the doctrine of the celebrated case of *Summers v. Tice*, 33 Cal.2d 80 (1948). The Court's decision was a response to needs which arise when ". . . advances in science and technology create fungible goods which may harm consumers and which cannot be traced to any specific producer." 26 Cal.3d at 610. Faced with a problem which did not fit neatly within any existing judicial doctrine, the California Supreme Court recognized that it could "either . . . adhere to prior doctrine, denying recovery to those injured by such products, or . . . fashion remedies to meet these changing needs." 26 Cal.3d at 610. Applying the principle set forth in Justice Traynor's concurring opinion in *Escola v. Coca Cola Bottling Co.*, 24 Cal.2d 453, 467-468 (1944),[1] the Court chose the latter course of action.

B. The Problem before the California Supreme Court.

The portion of the California Supreme Court's majority opinion which is reproduced in Appendix A provides a good summary of the problem before that court.

C. The Decision of the California Supreme Court.

As stated above, the California Supreme Court modified the doctrine of *Summers v. Tice* to provide a remedy for injuries to DES daughters who cannot identify the manufacturer of the drug that their mothers ingested. Consistent with the doctrine of *Summers v. Tice*, the California Supreme Court fashioned a remedy which shifts the burden of proof for causation to the defendants. Upon a showing that the plaintiff has "joined in the action the manufacturers of a substantial share of the DES which her mother might

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[1]The California Supreme Court, in its majority opinion, stated:

> "Just as Justice Traynor in his landmark concurring opinion in *Escola v. Coca Cola Bottling Co.*, (1944) 24 Cal.2d 453, 467-468, recognized that in an era of mass production and complex marketing methods the traditional standard of negligence was insufficient to govern the obligations of manufacturer to consumer, so should we acknowledge that some adaption of the rules of causation and liability may be appropriate in these recurring circumstances." 26 Cal.3d at 610.

have taken," the burden of proof as to who actually manufactured the injury-producing drug shifts to the defendants. Any defendants who cannot demonstrate that they could not have made the product ingested by plaintiff's mother are held liable for the cost of plaintiff's injuries. Unlike the doctrine of *Summers v. Tice*, the *Sindell* decision does not hold such defendants jointly and severally liable for the court's judgment. Deciding that joint and several liability would be too harsh in this context, the California Supreme Court held that "[e]ach defendant will be liable for the proportion of the judgment represented by its share of that market . . ." The Court decided that by apportioning liability for damages by market share, each manufacturer's liability would, ultimately, be "approximately equivalent to the damages caused by the DES that it manufactured." 26 Cal.3d at 617.

Following this decision, Petitioners asserted constitutional arguments in petitions for rehearing. The California Supreme Court denied these petitions without opinion.

REASONS FOR DENYING WRIT.

I.

THE UNITED STATES SUPREME COURT DOES NOT HAVE JURISDICTION TO HEAR PETITIONERS' COMMERCE CLAUSE AND SUPREMACY CLAUSE CLAIMS BECAUSE THESE CLAIMS WERE NOT PROPERLY RAISED AND PRESERVED IN THE STATE COURTS BELOW.

28 U.S.C., §1257(3) provides:

> "Final judgments or decrees rendered by the highest court of a State in which a decision could be had, may be reviewed by the Supreme Court as follows: . . .
>
> (3) By writ of certiorari, . . . where any title, right, privilege or immunity is specially set up or claimed under the Constitution, . . ."

Petitioners claim that the *Sindell* decision violates the Equal Protection and Due Process Clauses[2] and is preempted by Article I, Section 8, Clause 3, and Article VI, Clause 2 of the Constitution of the United States.

It has long been established that the United States Supreme Court does not have jurisdiction to hear a case unless a "substantial" federal question has been raised and decided in the state court below. *Cardinale v. Louisiana*, 394 U.S. 437, 438 (1969).[3] Generally, the federal questions must be raised precisely as required by state practice. When the highest state court does not pass on the federal question, any failure to follow state practice will result in a denial of review. *In Re Lamkin*, 355 U.S. 59 (1957).

As a general rule, California requires that a constitutional question must be raised at the earliest opportunity or it will be deemed waived. *Hershey v. Reclamation Dist.*, 200 Cal. 550 (1927); *Preston v. Municipal Court*, 188 Cal.App. 2d

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[2]For purposes of this discussion, we concede that this Court has jurisdiction to hear the Equal Protection and Due Process claims. Although the Due Process and Equal Protection claims were not properly raised by Petitioners, the California Supreme Court's discussion of these claims gives this Court jurisdiction to hear them.

[3]"The rule that in cases coming from state courts, this court may review only those issues which were presented to the state court is not discretionary but jurisdictional." *Amalgamated Food Employee Union v. Logan Valley Plaza*, 391 U.S. 308, 344 (1968). [dissenting opinion].

76 (1961).[4] Furthermore, it may be waived directly or indirectly.[5] *Chesney v. Byram*, 15 Cal.2d 460 (1940); *People v. Workham*, 121 Cal.App.2d 533 (1953).

Petitioners raised their Commerce Clause and Supremacy Clause claims for the first time in their petitions for rehearing before the California Supreme Court. Raising a federal question for the first time in a petition for rehearing before a state's highest court is generally insufficient unless that court actually entertains the petition and expressly decides the question. *Radio Station WOW v. Johnson*, 326 U.S. 120, 128 (1945); *Hansen v. Denckla*, 357 U.S. 235, 243-244 (1958).[6] Because the California Supreme Court did not entertain the petitions for rehearing and did not decide the Commerce Clause and Supremacy Clause issues, this Court does not have jurisdiction to hear these claims.

Petitioners claim, however, that the petitions for rehearing before the California Supreme Court were their first opportunity to raise the Commerce Clause and Supremacy Clause issues "because the theory of liability reached by the court was so revolutionary and completely unanticipated."[7] Petitioners' reliance on the doctrine of "surprise" for this proposition is unsupportable. It simply cannot be

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[4]In both situations, the California Supreme Court refused to hear appellants' claims that the relevant statutes were unconstitutional. The Court in both cases stated:

> "A party questioning the constitutionality of a statute or its application must raise the constitutional issue at the earliest opportunity."

[5]Directly by admission or by consent, and indirectly by failure to present a claim. Here, Petitioners indirectly failed to raise their claims.

[6]In order to constitute a reviewable judgment under such circumstances, the order denying the petition for rehearing must be more than a cursory statement that the Petitioners' claims have been considered and denied. There must be language in the order denying the petition for rehearing that the federal question was considered and disposed of on the merits. In other words, the state court must discuss the issue "in such a way that the case could have been brought here had the questions been raised prior to the original disposition." *Radio Station WOW v. Johnson*, 326 U.S. at 128. Because the California Supreme Court denied the petitions for rehearing without opinion, the Commerce Clause and Supremacy Clause claims were not entertained and expressly decided under these rules.

[7]Petitioners Rexall Drug Company and Eli Lilly and Company, Petition at p. 7.

said that the remedy in the *Sindell* case was unanticipated. The *Sindell* remedy was merely an extension of the *Summers* doctrine[8] and, therefore, should have been anticipated.[9] Furthermore, Petitioners should have anticipated any Commerce Clause and Supremacy Clause claims in response to *any* remedy devised by the California Supreme Court in favor of Respondents. (For example, Petitioners claim that the *Sindell* decision is preempted by the Supremacy Clause because it frustrates the federal policy in favor of generic drugs.[10] The same claim, however, could have been made following the Court of Appeal's decision[11] or for that matter, any other decision in favor of Respondents.) And yet, Petitioners failed to raise any Supremacy Clause or Commerce Clause claims when they petitioned for rehearing before the Court of Appeals, or when they appealed the decision of the Court of Appeals to the California Supreme Court. As a result, Petitioners cannot persuasively argue that either the remedy or results of the decision of the California Supreme Court were unanticipated.

Petitioner Squibb also argues that its Commerce Clause and Supremacy Clause arguments were properly raised because Petitioners have shown that this Court has jurisdiction to hear certain other constitutional claims attacking the *Sindell* rule.[12] It is a well-settled rule that the Supreme Court only has jurisdiction to consider the denial of other federal rights flowing from a judgment when the judgment is before this Court under its *appellate* jurisdiction and where the other claims in question can be brought before the Court

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[8]Respondent urged the application of the *Summers v. Tice* doctrine from the beginning of the *Sindell* proceedings. This doctrine was raised at the Superior Court level in respondent's complaint and in points and authorities in opposition to Petitioners' demurrers.

[9]Petitioners surely cannot be understood to suggest that every turn the law takes is unanticipated.

[10]Petitioners Rexall Drug Company and Eli Lilly and Company, Petition at p. 21.

[11]The same is true of the rest of Petitioners' Commerce Clause and Supremacy Clause claims. All these claims could have been made following the Court of Appeal's decision. Petitioners' failure to raise them at that time constitutes waiver.

[12]Petitioner E. R. Squibb & Son, Inc., p. 21. Citing *Flournoy v. Weiner*, 321 U.S. 253, 263 (1944); *Prudential Insurance Co. v. Cheek*, 259 U.S. 530, 547 (1922).

under its certiorari jurisdiction. This Court, in *Cox Broadcasting Corp., et al. v. Cohn,* 420 U.S. 469, 487 (1975) n. 14, explained, "In finding we have *appellate* jurisdiction, we also take jurisdiction over any aspects of the case which would otherwise fall solely within our *certiorari* jurisdiction." [emphasis added]. Petitioner's attempt to apply this rule to *Sindell* is clearly erroneous. As stated above, this doctrine is applicable only when the Supreme Court has *appellate* jurisdiction over at least one issue which is properly before the Court. In this case, the only issues properly before the Court are Petitioners' Due Process and Equal Protection claims. Those claims are before the Court on writ of certiorari. Therefore, this doctrine cannot be used to provide this Court with jurisdiction over Petitioners' Commerce Clause and Supremacy Clause claims.

II.

THE SINDELL DECISION DOES NOT DEPRIVE PETITIONERS OF DUE PROCESS OF LAW.

The Fourteenth Amendment provides that "No state shall . . . deprive any person of life, liberty, or property, without due process of law." This constitutional provision has been interpreted to provide both procedural and substantive safeguards.

A. The Sindell Decision Does Not Deprive Petitioners of Procedural Due Process.

Petitioners argue that the *Sindell* decision creates a rule of evidence relating to causation which deprives them of procedural due process.

Although the due process right to a hearing is generally found to embrace the right to present evidence, a state has considerable power to make or change rules which govern the introduction of evidence at trial to prove a particular issue. *Luria v. United States*, 231 U.S. 9 (1913).

(1) The Sindell Decision Does Not Create a Conclusive Presumption of Causation.

Corpus Juris Secundum, Vol. 31A, Evidence, §115, p. 197, distinguishes between conclusive and rebuttable presumptions as follows:

> "A conclusive presumption is a rule of substantive law, rather than of evidence, while a disputable or rebuttable presumption is a species of evidence that may be accepted or acted upon when there is no other evidence to uphold the contention for which it stands, or one which may be overcome by other evidence. When a statute makes a presumption conclusive, it cannot be rebutted by evidence." [footnotes omitted].

These definitions make it clear that the *Sindell* rule cannot be classified as a conclusive presumption of causation. The *Sindell* rule simply shifts the burden of proof to the defendant drug manufacturers when the plaintiff cannot identify which company manufactured the DES that her mother ingested. Under this rule, each defendant drug manufacturer has the opportunity to demonstrate "that it could not have made the product which caused the plaintiff's injuries."[13] Because each defendant is allowed to introduce such evidence, the *Sindell* decision can, at most, be interpreted as creating a rebuttable presumption of causation.[14]

(2) As Either a Rebuttable Presumption of Causation or an Allocation of the Burden of Proof, the Sindell Decision Does Not Deprive Petitioners of Procedural Due Process.

In civil cases, procedural due process requires that rebuttable presumptions and allocations of the burden of proof

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[13]26 Cal.3d at 612. Petitioners contend that the *Sindell* decision, by eliminating market share data as a means of showing lack of causation, effectively deprives them of *all* evidence that could be used to show they could not have caused plaintiff's injury. This contention ignores ample evidence which can be used to show lack of causation, *e.g.*, evidence showing that (1) defendant did not manufacture DES at time of ingestion, (2) defendant did not sell DES in the state where the drug was ingested, (3) defendant did not sell DES to the pharmacy from which the drug was purchased, (4) defendant did not manufacture dosages the size, shape or color of those ingested, etc.

[14]Assuming the *Sindell* decision can possibly be interpreted as an irrebuttable presumption, there is authority to support its constitutionality against procedural due process attack. The Court, in *Usery v. Turner Elkhorn Mining Co.*, 428 U.S. 1 (1976) upheld the constitutionality of a federal statute making X-ray or clinical evidence of complicated pneumonociosis (black lung disease) a conclusive presumption of total disability and death due to said disease. The Court stated:

> "We cannot say that it would be irrational for Congress to conclude that impairment of health alone warrants compensation."

satisfy the standard of "rationality." The application of this standard in response to a due process attack upon rebuttable presumptions, allocations of the burden of proof and other evidentiary limitations has been comprehensively discussed by Justice Marshall, writing for the majority, in *Usery v. Turner Elkhorn Mining Co.*, 428 U.S. 1 (1976).

Usery v. Turner Elkhorn Mining Co. involved a due process[15] challenge to certain evidentiary rules of a federal statute which provide a remedy to coal workers suffering from pneumonociosis (black lung disease). Under the statute, a coal mine operator is liable for death or total disability due to pneumonociosis contracted during employment in the operator's mine. Two coal mine operators challenged certain evidentiary rules designed to establish the element of causation. The provisions of the statute creating rebuttable presumptions of causation are summarized by the Court at 428 U.S. 11-12.

A comparison of the rebuttable presumptions in *Turner* with the *Sindell* rule reveals that the evidentiary rules[16] and

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[15]Due Process Clause of the Fifth Amendment to the U.S. Constitution.

[16]The major similarities between the *Turner* rebuttable presumptions and the rule of *Sindell* are as follows:

a. In *Turner*, the plaintiff coal miner or his survivors can shift the burden of proof for causation to the defendant coal mine operator by showing employment in the coal mines for a certain number of years. Under the rule of *Sindell*, a plaintiff DES daughter can shift the burden of proof for causation to the defendant drug companies by showing that she has joined in the action the manufacturers of a substantial share of the DES which her mother might have taken.

b. Like the defendants in *Turner*, the defendants in *Sindell* have the opportunity to introduce evidence to show the lack of causation.

c. The statute in *Turner* and the rule of *Sindell* both place a limitation on the type of evidence that a defendant can use to show lack of causation. The statute in *Turner* allows a plaintiff coal miner to use evidence of chest X-rays to trigger an irrebuttable presumption as to disability and death due to pneumonociosis (see 428 U.S. at 10-11), yet provides that none of the rebuttable presumptions in the statute can be defeated solely on the basis of such evidence, *e.g.*, the presumption that death was due to pneumonociosis (which is triggered by proof that a miner with 10 or more years' employment in the mines died from a "respirable disease") cannot be rebutted solely by evidence of

the due process issues[17] in both cases are very similar. Despite due process arguments almost identical to those advanced by Petitioners in *Sindell*, the *Turner* court upheld the constitutionality of all the evidentiary presumptions in the federal statute. The Court articulated the following standard for testing presumptions involving economic regulation of civil matters:

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a chest X-ray indicating the pneumonociosis was not the cause of death. 428 U.S. at 11-12. The *Sindell* decision allows a plaintiff DES daughter to use "market share" as evidence to trigger a shift in the burden of proof as to causation, yet does not allow a defendant drug manufacturer to show lack of causation solely on the basis of "market share" data.

d. Finally, both the statute in *Turner* and the rule of *Sindell* are cost-spreading devices which operate with less than perfect mathematical accuracy in individual cases. The statute in *Turner* could potentially hold a coal mine operator liable for pneumonociosis that was not contracted in his mines. Under the terms of the statute, a coal mine operator who cannot disprove causation can be held liable for death or disability benefits of a coal miner who contracted pneumonociosis while employed by a former employer or who never actually contracted pneumonociosis at all. Under the rule of *Sindell*, a defendant drug manufacturer who fails to show lack of causation can be held liable for a proportion of the judgment represented by its share of the DES market even though it may not have manufactured the particular DES that was ingested by the plaintiff's mother.

[17]The following are among the due process arguments that are common to the Petitioners in *Sindell* and the defendants in *Turner*:

a. The presumptions and limitations on rebuttal evidence constitutionally impair the defendant's ability to defend against the claims. 428 U.S. at 12.

b. The rules operate in an arbitrary and irrational manner by holding particular defendants liable for injuries they may not have actually caused. 428 U.S. at 18.

c. The rules will unfairly burden certain members of the industry. 428 U.S. at 18.

d. The rules create an improper method of cost-spreading. 428 U.S. at 19.

e. The facts triggering the operation of the presumptions are arbitrary (*i.e.*, in *Turner*, the 10 or 15 year period; in *Sindell*, a substantial proportion of the DES market). 428 U.S. at 29.

f. The evidentiary limitation denies defendants of due process because the evidence (i.e., in *Turner*, X-ray evidence; in *Sindell*, market share data) is frequently the sole evidence they can marshal to rebut the claim in question. 428 U.S. at 31.

> "That a legislative presumption of one fact from evidence of another may not constitute a denial of due process of law or a denial of the equal protection of the law it is only essential that there shall be some rational connection between the fact proved and the ultimate fact presumed, and that the inference of one fact from proof of another shall not be so unreasonable as to be a purely arbitrary mandate." 428 U.S. at 28.

In *Sindell*, the shifting of the burden of proof for causation is triggered by proof that the plaintiff has joined a "substantial" share of the manufacturers of the DES that her mother might have ingested. The issue is whether there is at least "some rational connection" between proof that a "substantial" share of the manufacturers have been joined and the presumption that one of the defendants so joined is actually responsible for plaintiff's injuries. In light of the Court's holding in *Turner*, the answer is clearly yes. A presumption that one of several defendants caused an injury (based upon proof that a "substantial share" of the possible defendants have been joined in the action) is not any more "arbitrary" or "irrational" than a presumption that a miner died due to pneumonociosis (based on proof that he worked in the mines for ten years and died of a "respirable disease").[18] In fact, the possibility of error under the *Sindell* rule is actually smaller than that under the statute in *Turner*. Because the defendants in *Sindell* are free to implead as many other manufacturers as they like, the possibility that one of the defendants before the court did not actually cause the plaintiff's injury can, virtually, be eliminated.

It is important to recognize that *Turner* does not require that the rules of law relating to causation match liability and actual responsibility for injury with mathematical accuracy. Responding to the argument that the retroactive application of the statute creates the possibility that a coal mine operator may be held liable for injuries that he did not actually cause, the Court stated:

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[18]In response to the coal mine operator's attack on proof of duration of employment as the basis of the presumption, the *Turner* court stated that as long as the durational requirement is not "purely arbitrary . . . no greater mathematical precision is required." 428 U.S. at 28.

> "We find, however, that the imposition of liability for effects and disabilities bred in the past is justified as a rational measure to spread the costs of the employees' disabilities to those who have profited from the fruits of their labor — the operators and the coal consumers . . ." 428 U.S. at 18.
>
> ". . . It is enough to say that the Act approaches the problem of cost-spreading rationally; whether a broader cost-spreading scheme would have been wiser or more practical under the circumstances is not a question of constitutional dimension. See e.g. *Ferguson v. Skrupa*, 372 U.S. at 730-732; *Williamson v. Lee Optical Co.*, 348 U.S. at 488." 428 U.S. at 18.

Under this principle, the *Sindell* decision's less than perfect mathematical allocation of liability is constitutionally permissible. Allocation of liability based upon market share is clearly a rational method of spreading costs among the manufacturers who profited from the sale of DES. As a result, the *Sindell* rule, like the statute in *Turner*, is a permissible method of compensating innocent victims of a dangerous instrumentality and allocating to the defendant "an actual, measurable cost of his business." See 428 U.S. at 19.

B. The Sindell Decision Does Not Deprive Petitioners of Substantive Due Process.

As previously stated, the *Sindell* decision shifts the burden of proof of causation to the defendants once the plaintiff DES daughter has shown that she was joined in the action a substantial share of the manufacturers of the DES that her mother might have ingested. Each defendant who fails to demonstrate that it could not have made the product which caused plaintiff's injuries is, then, held liable for the proportion of the judgment equal to its share of the DES market. Petitioners claim that this method of apportioning the judgment among the defendants who do not meet the burden of proof is "arbitrary and irrational" and, as a result, deprives them of substantive due process. This argument lacks merit.

(1) For Purposes of Due Process Review, the Sindell Decision Comes before the Court with a Presumption of Constitutionality.

The *Sindell* decision creates a rule of law affecting the economic and social welfare of the citizenry of California.

The rule was designed to provide a remedy for injuries suffered by innocent persons caused by a dangerous instrumentality and spread the costs of such injuries among the manufacturers who profited from its production.

It has long been established that a rule of law which adjusts the burdens and benefits of economic life for social welfare reasons comes before the Court with a presumption of constitutionality, and that the burden is on the one complaining to establish that the rule operates in an arbitrary and irrational manner. *Usery v. Turner Elkhorn Mining Co.*, 428 U.S. 1 (1976); *Ferguson v. Skrupa*, 372 U.S. 726 (1963); *Williamson v. Lee Optical Co.*, 348 U.S. 483, 487-488 (1955); *United States v. Carolene Products Co.*, 304 U.S. 144, 148 (1938).

In the majority opinion in *Ferguson v. Skrupa*, Justice Black emphasized that the due process constitutionality of a rule of law regulating matters of economics and social welfare is not dependent on the Court's conception of the wisdom of the regulation. The Court's opinion states:

> "Legislative bodies have broad scope to experiment with economic problems, and this Court does not sit to subject the state to an intolerable supervision hostile to basic principles of our government and wholly beyond the protection which the general clause of the Fourteenth Amendment was intended to secure." 372 U.S. at 730.
>
> ". . . We refuse to sit as a 'superlegislature to weigh the wisdom of legislation,' and we emphatically refuse to go back to the time when courts used the Due Process Clause 'to strike down state laws, regulatory of business and industrial conditions, because they may be unwise, improvident, or out of harmony with a particular school of thought.' " 372 U.S. at 731.

Finally, referring to a lawmaker's broad discretion in formulating rules which affect economic relationships and social welfare, Justice Powell, in his concurring opinion in *Usery v. Turner Elkhorn Mining Co.*, stated:

> "Nor does the Constitution require that legislation on economic matters be compatible with sound economics or even with normal fairness."

(2) The Sindell Decision Rests upon a Rational Basis.

The standard for testing the due process constitutionality of a rule of law regulating economic relationships and social welfare was specified in *United States v. Carolene Products Co.*, 304 U.S. 144 (1938). In that case, Justice Stone, writing for the majority, stated:

> "Regulatory legislation affecting ordinary commercial transactions is not to be pronounced unconstitutional unless in light of the *facts made known* and *generally assumed* it is of such a character as to preclude the assumption that it rests upon some *rational basis* within the knowledge and experience of the legislators." 304 U.S. at 152 [emphasis added].

In the *Sindell* opinion, the California Supreme Court made it very clear that it had a rational basis for apportioning the judgment in a DES case among defendants in proportion to their market share. After carefully considering the problem and analyzing each theory upon which Respondent requested relief, the California Supreme Court meticulously weighed the competing interests of the parties.[19]

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[19]In this weighing process, the Court considered the following interests:

a. The difficult problems created by a complex industrialized society, advances in science and technology which produce fungible goods which may harm innocent consumers and which cannot be traced to any specific producer. 26 Cal.3d at 610.

b. The inability of the consumer "to protect himself from serious, sometimes permanent, sometimes fatal injuries caused by deleterious drugs." 26 Cal.3d at 611.

c. The availability of evidence of causation. 26 Cal.3d at 611.

d. The ability of the parties to bear the cost of injury resulting from the manufacture of a defective product. 26 Cal.3d at 610-611.

e. The ability of the parties to discover, warn, guard against, and insure for risk of such injuries. 26 Cal.3d at 611.

f. The need to distribute the costs of such injuries to the manufacturer of the product and among the public as a cost of doing business. 26 Cal.3d at 611.

g. The possibility of holding a group of defendants liable for the injury, none of which was the actual manufacturer of the DES that the plaintiff's mother ingested. 26 Cal.3d at 611-612.

h. The possibility that each manufacturer's liability may not precisely conform to the injuries caused by its own products. 26 Cal.3d at 612-613.

i. The problems of determining market share with mathematical exactitude. 26 Cal.3d at 612-613.

j. The propriety of using market share as opposed to joint and several liability as a method of cost-spreading. 26 Cal.3d at 611.

After carefully weighing these interests, the Court decided that division of liability by market share was the best method of compensating the innocent victims of DES while fairly protecting the property interests of the defendant drug manufacturers. In making this decision, the California Supreme Court recognized that the facts before it made it *impossible* to create a rule that exactly matched liability with actual responsibility for injury. At the extremes, the Court was faced with either denying relief to DES daughters who cannot identify the manufacturer of the drug their mothers ingested or holding undiluted joint and several liability against the drug manufacturers. Refusing to accept either extreme, the California Supreme Court fashioned a rule of law that militates the inequities of both extremes. The Court adopted a rule of law apportioning damages in proportion to market share for those defendants who cannot demonstrate that they could not have caused plaintiff's injuries. Surely it is *not* irrational for a court to provide a remedy that protects the interests of both the plaintiff and the defendants in a tort case.

(3) When the Holding of Sindell Is Compared with the Holdings of Summers v. Tice, 33 Cal.2d 80 (1948) and Ybarra v. Spangard, 25 Cal.2d 486 (1944), Its Rationality Becomes Obvious.

Petitioners argue that the *Sindell* rule is "irrational and arbitrary" because it allows a court to hold them liable for injuries that their products did not actually cause. The error in this argument and the rationality of the *Sindell* court's method of apportioning damages becomes obvious when the potential for error under the *Sindell* rule is compared with the potential for error under the holdings of *Summers v. Tice* and *Ybarra v. Spangard*.

Petitioners do not question the constitutionality of *Summers v. Tice* or *Ybarra v. Spangard*. Both decisions have been part of California law for more than 30 years and have

been recognized by the Restatement of Torts[20] and almost every jurisdiction in the United States. Both cases hold independent tortfeasors jointly and severally liable for a plaintiff's injuries where neither the plaintiff nor the defendants can identify the particular tortfeasor who actually caused the plaintiff's injuries. Under the doctrines of both cases, there is potential for a 100% error in matching liability with actual responsibility for the harm (*i.e.*, a single innocent defendant can be held liable for 100% of the harm caused by another). For example, assume D1, D2, and D3 negligently shoot rifles in P's direction. Assume that P is severely injured by a single bullet from D3's gun but neither P, D1, D2, or D3 can prove that fact. Also assume D2 and D3 are judgment proof. Applying rule of *Summers v. Tice,* all three defendants are jointly and severally liable for P's injuries. Under the rule of joint and several liability, P may recover 100% of his damages from D1 thus creating a 100% error in matching liability with actual responsibility for harm.

Under the *Sindell* rule, the potential for error is much smaller. Under *Sindell,* the potential error with respect to a single innocent defendant is equal to his market share. For example, assume D1, D2 and D3 all negligently produced DES. Also assume respective market shares of 5%, 5% and

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[20]Restatement, Second, Torts §433B(3). It should be noted that the Restatement not only recognizes the doctrine of *Summers v. Tice* and *Ybarra v. Spangard* but also the need to make future modifications of this doctrine. Restatement, Second, Torts §433B(3) Comment 3(h) states:

> "It is possible that cases may arise in which some modification of the rule stated may be necessary because of complications arising from the fact that one of the actors involved is not or cannot be joined as a defendant, or because of the effect of lapse of time, or because of substantial differences in the character of the conduct of the actors or the risks which they have created. Since these cases have not arisen, and the situations which might arise are difficult to forecast, no attempt is made to deal with such problems in this section. The rule stated in Subsection (3) is not intended to preclude possible moderations if such situations call for it."

The California Supreme Court, in *Sindell,* modified the doctrine of *Summers v. Tice* and *Ybarra v. Spangard* in response to the precise circumstances anticipated by the Restatement above.

90%. Assume that the DES that P's mother ingested was produced by D3 but neither P, D1, D2 nor D3 can prove this fact. Applying the rule of *Sindell*, P, at most, could recover 5% of his damages from D1. The *Sindell* rule, therefore, reduces the matching error with respect to a single innocent defendant from 100% to a percentage equal to the market share of that defendant.

Keeping in mind that Petitioners have not challenged the constitutionality of either *Summers v. Tice* or *Ybarra v. Spangard* and that the *Sindell* method of allocating liability actually reduces the potential for error created by the well-established doctrine of these two cases, Petitioners' substantive due process arguments are not persuasive.

III.

THE SINDELL DECISION DOES NOT DENY PETITIONERS EQUAL PROTECTION OF THE LAWS.

The Fourteenth Amendment provides that "No state shall . . . deny to any person within its jurisdiction the equal protections of the laws."

A. For Purposes of Equal Protection Review, the Sindell Decision Comes before the Court with a Presumption of Constitutionality.

As discussed in Section II B (1) above, the *Sindell* decision is a rule of law affecting the economic and social welfare of the citizenry of California. The standards for reviewing rules affecting matters of economics and social welfare under the Equal Protection Clause are similar to the standards for reviewing such rules under the Due Process Clause. The major difference is that the Equal Protection review tests the rationality of the "classifications" drawn by the rule of law.

This Court, in *City of New Orleans v. Duke's*, 427 U.S. 297 (1976), stated:

> "When local economic regulation is challenged solely as violating the Equal Protection Clause, this Court consistently defers to legislative determinations as to the desirability of particular statutory discriminations. See, *e.g., Lehnhausen v. Lake Shore Auto Parts Co.*, 410 U.S. 356 (1973). Unless a classification trammels fundamental personal rights or is drawn upon

> inherently suspect distinctions such as race, religion, or alienage, *our decisions presume the constitutionality* of the statutory discriminations and require only that the classification challenged be rationally related to a legitimate state interest. States are accorded wide latitude in the regulation of their local economies under their police powers, and rational distinctions may be made with substantially less than mathematical exactitude.
>
> . . . In short, the judiciary may not sit as a superlegislature to judge the wisdom or desirability of legislative policy determinations made in areas that neither affect fundamental rights nor proceed along suspect lines, See, *e. g., Day-Brite Lighting, Inc. v. Missouri,* 342 U.S. 421, 423 (1952); in the local economic sphere, it is only the invidious discrimination, the wholly arbitrary act, which cannot stand consistently with the Fourteenth Amendment. See, *e. g., Ferguson v. Skrupa,* 372 U.S. 726, 732 (1963)." 427 U.S. at 303-304. [emphasis added].

B. The Classifications Drawn by the Sindell Decision Are Rationally Related to a Legitimate State Interest.

Petitioners argue that the *Sindell* rule treats them differently than defendants in other tort cases.[21] As shown below, the difference in treatment is "rationally related to a legitimate state interest."

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[21]Upjohn argues that the *Sindell* rule discriminates against petitioners on the basis of wealth. Upjohn bases its argument on the following portion of the California Supreme Court's opinion in *Sindell*:

> "From a broader policy standpoint, defendants are better able to bear the cost of injury resulting from the manufacture of a defective product." 26 Cal.3d at 611.

The California Supreme Court's intent in making this statement is clear. The statement merely considers one of the factors that courts have used for decades to decide tort cases — which party (plaintiff or defendant) can best bear the cost of the injury. This consideration cannot possibly be construed to indicate the intent to create a discriminatory classification among similarly situated defendants. At most, it treats the plaintiff and defendants differently. But because plaintiff and defendants are obviously not parties who are "similarly situated," a rule treating them differently does not raise an actionable Equal Protection issue.

It is undisputable that a state has a legitimate interest in compensating its citizens for injuries caused by dangerous products. The *Sindell* rule accommodates this interest by shifting the burden of proof for causation to the defendants once the plaintiff has shown that she has joined in the action a substantial share of the manufacturers of the DES that her mother might have taken. Why should such defendants be treated differently than defendants in other tort cases? The answer is simple. The rules are different because the circumstances of a DES daughter's injuries are different than the circumstances of the injuries in most tort cases.

Ms. Sindell was injured by a drug manufacturer, one of possibly 200 drug manufacturers, which she cannot identify because the product that caused her injuries was fungible and did not produce discoverable damage to her until almost twenty years after its purchase and ingestion by her mother.

The California Supreme Court was faced with the difficult choice between denying compensation to plaintiffs like Ms. Sindell or fashioning a new rule of law which adapts to the unusual circumstances of their injuries. The California Supreme Court chose the latter alternative and fashioned a remedy which shifts the burden of proof and apportions damages on the basis of "market share."[22] Because the

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[22]Upjohn argues that a rule based on "market share" and "substantial share" is so unworkable and uneven that certain defendants are deprived of Equal Protection of the Laws. The California Supreme Court effectively rebuts this argument by stating:

> "But just as a jury cannot be expected to determine the precise relationship between fault and liability in applying the doctrine of comparative fault (*Li v. Yellow Cab Co.* (1975) 13 Cal.3d 804) or partial indemnity (*American Motorcycle Assn. v. Superior Court*,(1978) 20 Cal.3d 578), the difficulty of apportioning damages among the defendant producers in exact relation to their market share does not seriously militate against the rule we adopt. As we said in *Summers* with regard to the liability of independent tortfeasors, where a correct division of liability cannot be made 'the trier of fact may make it the best it can.' (33 Cal.2d at p. 88)."

The California Supreme Court's position is supported by the following passage of the majority opinion of *City of New Orleans v. Duke's*, 427 U.S. 297, 303 (1976):

> "States are accorded wide latitude in the regulation of their local economics under their police powers, and rational distinctions may be made with *substantially less* than mathematical exactitude." [emphasis added].

circumstances of Ms. Sindell's injuries prevented her from identifying the particular tortfeasor who actually caused her harm, the California Supreme Court had no choice but to depart from the rules generally used in tort cases to establish the element of causation. Such departures are not uncommon to California law. As stated earlier, the California Supreme Court made exactly the same policy judgment in *Summers v. Tice* and *Ybarra v. Spangard*. Like the decisions in *Summers* and *Ybarra*, the decision in *Sindell* was made after carefully weighing the interests of the State, the plaintiff and the defendants. See discussion of Section II B (2), *supra*. The *Sindell* rule was drawn so carefully that it creates a potential for error (with respect to a single innocent defendant) which is actually smaller than that created by either *Summers* or *Ybarra*. See discussion in Section II B (3), *supra*. Because the *Sindell* rule reduces the potential for error and addresses the same circumstances as the well-established doctrine of *Summers* and *Ybarra*, an Equal Protection challenge to *Sindell* can, necessarily, be no more persuasive than an Equal Protection challenge to *Summers* and *Ybarra*.

IV.

THE SINDELL DECISION IS NOT INVALID UNDER THE SUPREMACY CLAUSE.

Article VI, Clause 2 (the "Supremacy Clause") provides that the "Constitution and the laws of the United States which shall be made in pursuance thereof; and all Treaties made or which shall be made under the authority of the United States shall be the supreme law of the land . . ." Thus to the extent that Congress has exercised one of its powers, any inconsistent state law is prohibited.

In the recent United States Supreme Court decision in *Ray v. Atlantic Richfield Co.*, 435 U.S. 151 (1978), this Court drew from prior decisions, *e.g.*, *Jones v. Rath Packaging Co.*, 430 U.S. 519, 525 (1977) and *Rice v. Sante Fe Elevator Corp.*, 331 U.S. 218 (1947) and enunciated five areas for inquiry for determining whether Congress intended to foreclose state legislation in a particular area. 435 U.S. at 157. That Court noted that the Congressional purpose to supersede the police power of the states

". . . may be evidenced in several ways. [1] The scheme of federal regulation may be so persuasive as to make reasonable the inference that Congress left no room for the States to supplement it . . . [2] Or the Act of Congress may touch a field in which the federal interest is so dominant that the federal system will be assumed to preclude enforcement of state laws on the same subject . . . [3] Likewise, the object sought to be obtained by the federal law and the character of obligations imposed by it may reveal the same purpose . . . [4] Even if Congress has not completely foreclosed state legislation in a particular area, a state statute is void to the extent that it actually conflicts with a valid federal statute. A conflict will be found where compliance with both federal and state regulations is a physical impossibility . . . or [5] where the state 'law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress . . .' " 435 U.S. at 158 [citations omitted; numbers added for emphasis].

A. The Scheme of Drug Regulation Is Not so Persuasive as to Make Reasonable the Inference That Congress Left No Room for the State to Supplement It.

Although the introduction of new drugs is extensively regulated by the Federal government, a long line of United States Supreme Court cases have held that Congress has left room for state and municipal regulations. In *Corn Products Refining Company v. Eddy*, 249 U.S. 427 (1919), this Court upheld a state statute that supplemented the Federal Drug and Cosmetic Act.[23] Furthermore, numerous cases have recognized state civil remedies where personal injury, death or property damage result to consumers from dangerous

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[23]The most recent decision of this Court on this matter upheld the right of a state to supplement the registration scheme of the Federal Drug and Cosmetic Act. *Whalen v. Roe*, 429 U.S. 589 (1977).

drugs.[24] See, *e.g.*, *State of Florida Ex Rel., Broward County v. Eli Lilly Co.*, 329 F. Supp. 364, 365 (1971) and cases cited therein. The federal scheme of drug regulation is simply not so persuasive to infer that the state may not supplement it with a rule of civil liability such as *Sindell*.

B. The Federal Interest in Regulating Drugs Is Not so Dominant That the Federal System Should Be Assumed to Preclude Enforcement of State Laws on the Same Subject.

An act of Congress can demonstrate a federal interest so dominant that it precludes any state regulation of the same subject matter. In *Hines v. Davidowitz*, 312 U.S. 52 (1941), this Court found that a federal statute requiring the registration of aliens evidenced such an interest. After recognizing that the federal interest in regulating foreign affairs is constitutionally paramount, the Court in *Hines* invalidated a Pennsylvania alien registration law. The Court noted:

> "The Supremacy of the national power in the general field of foreign affairs, including power over immigration, naturalization and deportation is made clear by the Constitution." 312 U.S. at 62.

There is no similar federal interest that precludes the remedy provided by the *Sindell* rule. Unlike the area of alienage and naturalization, rules governing tort liability for defective products have been traditionally considered within the province of state governments.

C. The Rule in the Sindell Case Does Not Purport to Govern the Same Area and Does Not Impose an Obligation Similar to Those Imposed by the Federal Drug and Cosmetic Act.

A clear and manifest purpose of Congress to supersede the police power of a state may be shown by "the object

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[24]The legislative history of the Federal Food and Drug Act indicates that an express provision for a private right of action for damages was included in an early version of the bill but was omitted from all later versions after being attacked on the ground that it would create an unnecessary federal action *duplicative* of state remedies. *State of Florida Ex Rel. Broward County v. Eli Lilly & Co.*, 329 F. Supp. 364, 365, n. 2 (1971) citing Hearings on S 1944, before a Subcommittee of the on Commerce, U.S. Senate, 73d Cong., 2d Sess., pp. 10, 144, 219, 403, 431, 444 (1933).

sought to be obtained by the federal government and the character of obligations imposed on it may reveal the same purpose." *Southern R. Co. v. Railroad Commission,* 236 U.S. 439 (1915); *Charleston & W.C.R. Co. v. Varnville,* 237 U.S. 597 (1915). In the above cases, this Court struck down state statutes that purported "to prescribe additional regulation and what they may deem auxiliary provisions for the *same purpose.*" *Southern R. Co.,* 236 U.S. at 447 [emphasis added].

The *Sindell* rule is not an attempt to achieve the same purposes as the Federal Drug and Cosmetic Act, nor does it impose the same obligations as that Act. The Federal Drug and Cosmetic Act is concerned with the safety and efficacy of prescription drugs. The Act achieves this purpose through labeling, registration and disclosure requirements. The Act makes no attempt to define or prescribe a drug manufacturer's liability for injuries caused by defective products. *Orthopedic Equipment v. Eutsler,* 276 F.2d 455 (1960).

In contrast, the *Sindell* decision is merely a mechanism designed to equitably allocate responsibility for damage caused by a drug manufacturer's defective products. Its only purpose is to compensate innocent DES victims who cannot identify the manufacturer of the products that caused them harm.

Because the Federal Drug and Cosmetic Act does not purport to govern rules of civil liability arising from defective drugs and the *Sindell* decision does not purport to govern labeling, registration or disclosure requirements for drugs, the *Sindell* rule is not preempted because it attempts to govern the same area or impose the same obligations as an existing federal law.

D. The Sindell Decision Is Not in Direct Conflict with a Valid Federal Statute.

In the instant case, Petitioners made no claim (nor could they make such a claim) that the *Sindell* decision is in direct conflict with any federal authority; that is, that "any federal enactment is directly contradictory on [its] face . . . so that compliance with both is a literal impossibility." Tribe, American Constitutional Law, (1978 Ed.) §6-24, p. 377, 378.

E. The Sindell Decision Does Not Stand as an Obstacle to the Accomplishment and Execution of the Full Purposes and Objectives of Congress.

Petitioners contend that the *Sindell* decision must be set aside as a violation of the Supremacy Clause because it will frustrate the policies and objectives of the federal drug regulatory system. In support of this contention, Petitioners argue that *Sindell* is a chamber of horrors. They argue that the *Sindell* rule will create serious anti-competitive effects, tend to create and prolong monopoly and discourage the production of generic drugs. These arguments are not persuasive for a number of reasons.

Before proceeding further, it is interesting to note the unusual nature of Petitioners' arguments. Nowhere in Petitioners' arguments before the Supreme Court or in their petitions for a writ of certiorari have they denied (or even implied that they deny) that their products have caused thousands and perhaps millions of innocent women like Ms. Sindell serious bodily injury. Yet, Petitioners argue that a rule that imposes liability on them for these injuries is unfair because it may adversely affect their profitability. It is difficult to understand why it is "unfair" to make a person or an entity responsible for the consequences of its own actions.

(1) Anti-Competitive Effects.[25]

Petitioners' argument that the *Sindell* rule will adversely affect price competition among drug manufacturers is, at best, tenuous. Logically, it is difficult to understand how the *Sindell* rule will have any serious adverse effect on price competition. Because the rule apportions liability on the basis of market share, the production costs of small firms should be no more adversely affected than those of large firms. If anything, the California Supreme Court appears to have chosen a method of apportioning liability which minimizes the effects on price competition.

Petitioners also argue that the *Sindell* rule will drive small manufacturers out of business and create barriers to entry into the drug manufacturing industry. This argument suffers

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[25]Petition of Rexall Drug Company and Eli Lilly and Company at at p. 21.

from a fatal flaw: the objective of the federal regulatory system is *not* to protect manufacturers of *defective* products. The purpose of the Food, Drug and Cosmetic Act, 21 USC, §301, *et seq.*, is to protect consumers, who in the circumstances of modern industrialism are largely beyond self-protection. *62 Cases of Jam v. United States*, 340 U.S. 593 (1951). The *Sindell* rule does not impose liability on all manufacturers in the drug industry regardless of fault. It imposes liability *only* when a manufacturer has produced a defective product. If the *Sindell* rule forces anyone out of business, it will be manufacturers who produce too many defective products. If anything, the elimination or exclusion of such manufacturers will further, rather than frustrate, Congress' objective to protect helpless consumers.

Even assuming certain anti-competitive effects are created, the *Sindell* rule would not automatically be invalid under the Supremacy Clause as contrary to federal policies favoring competition. In the recent case of *Exxon Corp. v. Gov. of Maryland*, 437 U.S. 117 (1978), this Court addressed appellant Exxon's claim that certain anti-competitive effects of a Maryland statute violated the Supremacy Clause. Rejecting this argument, this Court stated:

> "We are, therefore, satisfied that . . . the broad implications of the Sherman Act cannot be fairly construed as a congressional decision to preempt the power of Maryland to enact this law. For if an adverse effect on competition were in and of itself enough to render a state statute invalid, the state's power to engage in economic regulation would be effectively destroyed." 437 U.S. at 132.

(2) Monopolistic Effects.

Petitioners' argument that the *Sindell* rule will tend to create and prolong monopoly[26] suffers from the same flaw as their argument that it will drive small manufacturers out of business and create barriers to entry. As stated above, there is nothing inherently evil about eliminating or excluding manufacturers of defective products from the drug industry. The purpose of federal drug regulations is to protect consumers of drug products, not manufacturers.

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[26]Petition of Upjohn at p. 27.

Petitioners cite *Sears Roebuck Co. v. Stiffel*, 376 U.S. 225 (1964) as authority for their monopoly argument. It should be noted that their reliance on this case for the proposition that they assert is both unpersuasive and unjustified. The issue in the *Sears* case was whether the state's unfair competition law was compatible with federal patent law where a mechanical device that was not entitled to a patent was the subject matter of an unfair competition action. This Court found that the statute was incompatible with the federal law because the application of the state's unfair competition law to the patent area "would . . . permit the state to block off from the public something that the federal law has said belongs to the public . . ." 376 U.S. at 231, 232. This case clearly does not apply to *Sindell*. The *Sears* case would apply only if there were a federal statute regulating when a person may or may not sue a drug company. There is, of course, no such statute.

(3) Effect on Production and Marketing of Generic Drugs.

From a logical point of view, Petitioners' argument — that the *Sindell* rule will frustrate federal policies favoring the production and marketing of generic drugs[27] — is no more persuasive than their arguments cited in Sections (1) and (2) above. As stated before, the rule of *Sindell* does not assign liability without fault. To be responsible for damages under this rule, a drug manufacturer *must* produce a defective product. Contrary to Petitioners' arguments, such a rule will more likely serve to further, rather than frustrate, Congress' objective to protect helpless consumers. Holding drug manufacturers liable for the injuries caused by their products will definitely provide incentives to produce safer drugs.

As authority for their argument that *Sindell* interferes with federal policies favoring the production and marketing of generic drugs, Petitioners cite certain statements contained in a Department of Health, Education and Welfare bulletin and made at hearings before the Subcommittee of the Committee on Labor and Public Welfare.[28] Petitioners argue that

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[27]Petition of Rexall Drug Company and Eli Lilly and Company at pp. 22, 23.

[28]Petition of Rexall Drug Company and Eli Lilly and Company at pp. 22, 23.

these statements constitute a "clear and manifest"[29] statement by Congress that no state rule, regulation or statute may burden (however indirectly) the production of generic drugs. The statements cited by Petitioners are clearly not sufficient to manifest such intent. Traditionally, courts have required a more definitive statement manifesting the congressional intent to preclude state involvement in a particular area. *Pharmaceutical Soc., State of N.Y., Inc. v. Lefkowitz*, 454 F. Supp. 1175, 1179 (1978); *Rice v. Sante Fe Elevator Corp.*, 331 U.S. 218, 230 (1947). Furthermore, the objectives of Congress are generally not frustrated by the imposition of liability for harm arising out of congressionally favored activities.[30] That is, of course, unless Congress has specifically exempted an activity from liability. *Sherlock, et al. v. Alling, Administrator*, 93 U.S. 99 (1876).

V.

THE SINDELL DECISION IS NOT A REGULATION AFFECTING INTERSTATE COMMERCE.

Article I, Section 8, Clause 3, of the United States Constitution provides: "[The Congress shall have the power] . . . To regulate Commerce . . . among the several States." This language has been interpreted to limit the States' ability to regulate interstate commerce.

Petitioners claim that the *Sindell* decision contravenes the Commerce Clause by creating an impermissible burden on interstate commerce. However, it is well-established that civil remedies — which only "indirectly" relate to or affect interstate commerce — are not "regulations" for purposes of the Commerce Clause.

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[29]Consideration of this claim begins with the recognition that the "historic police powers of the State were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." *Ray v. Atlantic Richfield Co.*, 435 U.S. at 157.

[30]There are many products and activities that are favored by Congress or by some department of the executive branch. Yet, manufacturers of these products and participants in these activities remain liable for the harm they cause. The defense industry is one such example. Certainly, Congress is interested in the production of the greatest number of weapons at the lowest cost. Just as certain, however, is the idea that the manufacturers of those weapons are liable for damages negligently caused during the production of those weapons.

The constitutionality of civil remedies under the Commerce Clause was thoroughly treated by this Court in *Missouri, Kansas & Texas v. Haber*, 169 U.S. 613 (1898), and in *Sherlock, et al. v. Alling, Administrator*, 93 U.S. 99 (1876). *Haber* involved a Kansas statute that made any shipper or importer of diseased cattle liable for all damages caused by those cattle. Under the terms of the statute, a prima facie case of liability was established upon proof that the allegedly diseased cattle were shipped into Kansas through an area below the thirty-seventh parallel. This presumption could be rebutted by demonstrating that the cattle had been kept in an area west of the twenty-second meridian or north of the thirty-fourth parallel.

The *Sherlock* case involved an action for damages under an Indiana statute giving a right of action in favor of the personal representative of one whose death was caused by the wrongful act or omission of another.

In both cases, defendants claimed that the state statutes were impermissible burdens on interstate commerce. The *Haber* and *Sherlock* courts rejected this argument after concluding that the statutes did not constitute a regulation within the meaning of the Commerce Clause. The *Sherlock* court concluded:

> "Legislation in a great variety of ways may affect commerce and persons engaged without constituting a regulation of it within the meaning of the Constitution." 93 U.S. at 103.

The Court justified this conclusion by stating:

> "The Indiana statute imposes no tax, proscribes no duty and in no respect interferes with any regulation for the navigation and use of vehicles. It only declares a general principle respecting the *liability* of all persons within the jurisdiction of the State *for torts* resulting in the death of parties injured. General legislation of those prescribing the liabilities or duties of citizens of a state without distinction as to pursuit or calling is not open to any valid objection because it may affect persons engaged in foreign or interstate commerce." 93 U.S. at 103 [emphasis added].

Citing the *Sherlock* decision, the *Haber* court stated:

> "It is said that the statute of Kansas giving a right of action for damages is, in itself a regulation of commerce among the States, and therefore, inconsistent with the power of Congress to regulate such commerce. But that statute is not within the meaning of the Constitution, nor in any just sense, a regulation of commerce among the states . . . It did nothing more than declare as a *rule of civil liability* in Kansas, that anyone driving, shipping or transporting or causing to be driven, shipped or transported, into or through any county, in that state, cattle liable to impart or capable of communicating Texas, splenic or Spanish fever to domestic cattle should be responsible to any person injured thereby." 169 U.S. at 625. [emphasis added].

In light of the similarities between *Haber* and *Sherlock* and *Sindell*,[31] it is clear that *Sindell* cannot be considered a regulation affecting interstate commerce. The *Sindell* decision does not prohibit any commerce among the states. It does nothing more than make drug manufacturers responsible for damage caused by a dangerous product. It simply fashions a rule of civil liability well within the state's inherent power to protect its citizenry. Moreover, the *Sindell* decision imposes no tax, proscribes no duty, and in no respect interferes with any regulations providing for the manufacture and distribution of drugs. For these reasons, the rule in the *Sindell* decision is not prohibited by Article I, Section 8, Clause 3 of the Constitution.

Because the *Sindell* rule is not a regulation affecting interstate commerce, it is unnecessary to address whether this decision is rationally related to a legitimate state end, whether the regulatory burden imposed on interstate commerce is outweighed by the state's interest, or whether there is a less burdensome alternative to the remedy chosen by the California Supreme Court.[32]

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[31]There are four important similarities between the rule of law in the *Sindell* case and statutes of *Haber* and *Sherlock*: (a) All create or allow causes of actions for negligent behavior; (b) all involve use of rebuttable presumptions; (c) all were challenged on commerce clause grounds; (d) all did not directly affect interstate commerce.

[32]Even if these issues were relevant, the discussion in Section III B clearly demonstrates that the *Sindell* rule is rationally related to a legitimate state goal, and that the California Supreme Court arrived at this decision after exhaustively weighing all relevant factors.

CONCLUSION.

For the reasons stated above, Respondent respectfully requests that Petitioners' Petitions for a Writ of Certiorari to the Supreme Court of California be denied.

Respectfully submitted,

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APPENDIX A.

The California Supreme Court Summarized the allegations in Respondent's complaint as follows:

"Between 1941 and 1971, defendants were engaged in the business of manufacturing, promoting and marketing diethylstilbesterol (DES), a drug which is a synthetic compound of the female hormone estrogen. The drug was administered to plaintiff's mother and the mothers of the class she represents[1] for the purpose of preventing miscarriage. In 1947, the Food and Drug Administration authorized the marketing of DES as a miscarriage preventative, but only on an experimental basis, with a requirement that the drug contain a warning label to that effect.

DES may cause cancerous vaginal and cervical growths in the daughters exposed to it before birth, because their mothers took the drug during pregnancy. The form of cancer from which these daughters suffer is known as adenocarcinoma, and it manifests itself after a minimum latent period of 10 or 12 years. It is a fast-spreading and deadly disease, and radical surgery is required to prevent it from spreading. DES also causes adenosis, precancerous vaginal and cervical growths which may spread to other areas of the body. The treatment for adenosis is cauterization, surgery, or cryosurgery. Women who suffer from this condition must be monitored by biopsy or colposcopic examination twice a year, a painful and expensive procedure. Thousands of women whose mothers received DES during pregnancy are unaware of the effects of the drug.

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[1]The plaintiff class alleged consists of "girls and women who are residents of California and who have been exposed to DES before birth and who may or may not know that fact or the dangers" to which they were exposed. Defendants are also sued as representatives of a class of drug manufacturers which sold DES after 1941.

In 1971, the Food and Drug Administration ordered defendants to cease marketing and promoting DES for the purpose of preventing miscarriages, and to warn physicians and the public that the drug should not be used by pregnant women because of the danger to their unborn children.

During the period defendants marketed DES, they knew or should have known that it was a carcinogenic substance, that there was a grave danger after varying periods of latency it would cause cancerous and precancerous growths in the daughters of the mothers who took it, and that it was ineffective to prevent miscarriage. Nevertheless, defendants continued to advertise and market the drug as a miscarriage preventative. They failed to test DES for efficacy and safety; the tests performed by others, upon which they relied, indicated that it was not safe or effective. In violation of the authorization of the Food and Drug Administration, defendants marketed DES on an unlimited basis rather than as an experimental drug, and they failed to warn us of its potential danger.[2]

Because of defendants' advertised assurances that DES was safe and effective to prevent miscarriage, plaintiff was exposed to the drug prior to her birth. She became aware of the danger from such exposure within one year of the time she filed her complaint. As a result of the DES ingested by her mother, plaintiff developed a malignant bladder tumor which was removed by surgery. She suffers from adenosis and must constantly be monitored by biopsy or colposcopy to insure early warning of further malignancy.

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[2]It is alleged also that defendants failed to determine if there was any means to avoid or treat the effects of DES upon the daughters of women exposed to it during pregnancy, and failed to monitor the carcinogenic effects of the drug.

The first cause of action alleges that defendants were jointly and individually negligent in that they manufactured, marketed and promoted DES as a safe and efficacious drug to prevent miscarriage, without adequate testing or warning, and without monitoring or reporting its effects.

A separate cause of action alleges that defendants are jointly liable regardless of which particular brand of DES was ingested by plaintiff's mother because defendants collaborated in marketing, promotion and testing the drug, relied upon each other's tests, and adhered to an industry-wide safety standard. DES was produced from a common and mutually agreed upon formula as a fungible drug interchangeable with other brands of the same product; defendants knew or should have known that it was customary for doctors to prescribe the drug by its generic rather than its brand name and that pharmacists filled prescriptions from whatever brand of the drug happened to be in stock.

Other causes of action are based upon theories of strict liability, violation of express and implied warranties, false and fraudulent representations, misbranding of drugs in violation of federal law, conspiracy and "lack of consent."

Each cause of action alleges that defendants are jointly liable because they acted in concert, on the basis of express and implied agreements, and in reliance upon and ratification and exploitation of each other's testing and marketing methods.

Plaintiff seeks compensatory damages of $1 million and punitive damages of $10 million for herself. For the members of her class, she prays for equitable relief in the form of an order that defendants warn physicians and others of the danger of DES and the necessity of performing certain tests to determine the presence of diseases caused by the

drug, and that they establish free clinics in California to perform such tests.

Defendants demurred to the complaint. While the complaint did not expressly allege that plaintiff could not identify the manufacturer of the precise drug ingested by her mother, she stated in her points and authorities in opposition to the demurrers filed by some of the defendants that she was unable to make the identification, and the trial court sustained the demurrers of these defendants without leave to amend on the ground that plaintiff did not and stated she could not identify which defendant had manufactured the drug responsible for her injuries. Thereupon, the court dismissed the action.[3] This appeal involves only five of ten defendants named in the complaint.[4]

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[3]There are minor variations in the procedures employed as to the various defendants. Thus, for example, Eli Lilly and Company filed a motion for summary judgment, or alternatively judgment on the pleadings, rather than a demurrer; the court treated the motion as a demurrer.

The demurrer of Abbott Laboratories, the first defendant to file a demurrer and the first to secure a dismissal, was sustained with leave to amend on the ground that plaintiff had failed to allege that a product manufactured by Abbott had caused her injuries (as opposed to the reason given by the trial court for sustaining the demurrers of the other defendants that plaintiff expressly stated that she could not identify a particular manufacturer). Upon plaintiff's failure to amend the complaint, the action was dismissed as to Abbott. A few days after the dismissal, plaintiff stated in a brief in opposition to the demurrers filed by defendants other than Abbott that she could not make the identification.

Abbott asserts that as to it the issue we consider on the appeal is not properly raised because plaintiff's statement that she could not identify the manufacturer was not made until after the action had been dismissed as to Abbott. This contention is without merit. Plaintiff's failure to amend her complaint after Abbott's demurrer was sustained with leave to amend was based upon her inability to identify a specific manufacturer. Clearly, Abbott interpreted the complaint in this fashion, for it moved for dismissal on the ground that the complaint alleges that plaintiff "does not know the identity of the drug . . . ingested" by her mother. Thus, Abbott may not now claim that the complaint is insufficient to raise the issues involved in this appeal.

The trial court did not determine other issues raised by the complaint, such as whether the case was properly brought by a class action.

[4]Abbott Laboratories, Eli Lilly and Company, E.R. Squibb and Sons, The Upjohn Company, and Rexall Drug Company are respondents. The action was dismissed or the appeal abandoned on various grounds as to other defendants named in the complaint; *e.g.*, one defendant demonstrated it had not manufactured DES during the period plaintiff's mother took the drug.

Plaintiff Maureen Rogers filed a complaint containing allegations generally similar to those made by Sindell. She seeks compensatory and punitive damages on her own behalf, and on behalf of a class described in substantially the same terms as in Sindell's complaint, as well as equitable relief comparable to that sought by Sindell. The trial court sustained demurrers of E. R. Squibb & Sons, the Upjohn Company, and Rexall Drug Company.[5] Subsequent to the dismissal of her action against these defendants, Rogers amended the complaint to allege that Eli Lilly and Company, one of the defendants named in her complaint, has manufactured the drug used by her mother. Although Sindell's action and the present case have been consolidated on appeal, much of the discussion which follows will apply to Rogers only if she does not succeed in establishing that Eli Lilly and Company manufactured the DES taken by her mother. "Plaintiff" as used in this opinion refers to Sindell, and we discuss only the allegations of Sindell's complaint.

This case is but one of a number filed throughout the country seeking to hold drug manufacturers liable for injuries allegedly resulting from DES prescribed to the plaintiffs' mothers since 1947.[6] According to a note in the Fordham Law Review, estimates of the number of women who took the drug during pregnancy ranged from 1½ million to 3 million. Hundreds, perhaps thousands, of the daughters of these women suffer from adenocarcinoma, and the incidence of vaginal adenosis among them is 30 to 90 percent. (Comment, *DES and a Proposed Theory of Enterprise Li-*

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[5]While the trial court did not specify the ground upon which the demurrers were sustained, the points and authorities filed by the parties emphasized the failure of Rogers to identify a particular manufacturer as the source of her injuries, and we may assume for the purpose of this appeal that this was the basis of the court's order.

[6]DES was marketed under many different trade names.

ability (1978) 46 Fordham L. Rev. 963, 964-967 [hereafter Fordham Comment].) Most of the cases are still pending. With two exceptions,[7] those that have been decided resulted in judgments in favor of the drug company defendants because of the failure of the plaintiffs to identify the manufacturer of the DES prescribed to their mothers.[8] The same result was reached in a recent California case. (*McCreery v. Eli Lilly & Co.* (1978) 87 Cal. App. 3d 77, 82-84.) The present action is another attempt to overcome this obstacle to recovery." 26 Cal. 3d at 595-597.

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[7]In a recent New York case a jury found in the plaintiff's favor in spite of her inability to identify a specific manufacturer of DES. An appeal is pending. (*Bichler v. Eli Lilly and Co.* (Sup. Ct. N.Y. 1979).) A Michigan appellate court recently held that plaintiffs had stated a cause of action against several manufacturers of DES even though identification could not be made. (Abel v. Eli Lilly and Co. (decided Dec. 5, 1979) Docket No. 60497.) That decision is on appeal to the Supreme Court of Michigan.

[8]*E.g., Gray v. United States* (S.D. Texas 1978) 445 F.Supp. 337. In their briefs, defendants refer to a number of other cases in which trial courts have dismissed actions in DES cases on the ground stated above.

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Nos. 80-157, 80-158, 80-170, 80-172

IN THE

Supreme Court of the United States

OCTOBER TERM, 1980

ABBOTT LABORATORIES, *et al., Petitioners,*

v.

JUDITH SINDELL, *et al., Respondents.*

On Petition For A Writ Of Certiorari To The Supreme Court Of California

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BRIEF *AMICUS CURIAE* OF THE AMERICAN INSURANCE ASSOCIATION IN SUPPORT OF PETITIONS FOR WRIT OF CERTIORARI

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QUESTIONS PRESENTED

1. Whether the market share rule announced by the California Supreme Court is a denial of due process because it is unfair, irrational and unworkable.

2. Whether the market share rule is in conflict with the Food and Drug Act which is designed to facilitate the widespread and inexpensive distribution of generic drugs.

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On Petition For A Writ Of Certiorari To The Supreme Court Of California

---

BRIEF *AMICUS CURIAE* OF THE AMERICAN INSURANCE ASSOCIATION IN SUPPORT OF PETITIONS FOR WRIT OF CERTIORARI

The American Insurance Association ("AIA"), with the consent of all parties,* files this brief *amicus curiae* in support of the petitions for a writ of certiorari to review the judgment of the California Supreme Court.

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* The written consents of counsel for the parties have been filed with the Clerk of the Court.

INTEREST OF THE AMICUS CURIAE

AIA is a trade association whose 150 member companies account for a substantial proportion of the product liability insurance in effect in the United States today. Many of its members have written policies for drug companies, including companies that have manufactured diethylstilbestrol ("DES"). Many hope to be able to offer insurance coverage to drug companies in the future. AIA files this brief in support of the petitions for certiorari because California's "market share" rule will, if allowed to stand, have intolerable consequences for the insurance industry, the tort system, and the nation as a whole.

One consequence of the market share rule is to make it virtually impossible for insurers to issue general commercial liability policies to drug companies. This type of policy must ontain an indemnity and a defense obligation. Under the market share rule, neither of these can be estimated with tolerable accuracy. The indemnity obligation cannot be priced because one firm will as a matter of course be held responsible for losses caused by any other firm that sells the same products. The defense obligation cannot be priced because the market share rule will create enormous and uncontrollable litigation costs merely to sort out the shares of all defendants before the substantive issues in these cases — difficult enough in their own right — are even reached.[1] The

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[1] The administrative costs implicit in this litigation are fast becoming common knowledge. *See* M. Kinsley, *Fate and Lawsuits,* New Republic, June 14, 1980, 20 at 21:

> A 1977 government study of product liability [Interagency Task Force on Product Liability, Final Report on the Insurance Study, U.S. Dep't of Commerce PB-263-600] concluded that each dollar paid to plaintiffs costs defendants another 42 cents in expenses, almost all for lawyers, and that about 35

absence of insurance will surely drive small drug manufacturers out of the market and will increase the reluctance of all drug manufacturers to introduce new and life-saving drugs. The breakdown of private insurance markets in the swine flu vaccine program is already a matter of public record.[2]

The market share rule also threatens to have an enormous *retroactive* impact upon both the pharmaceutical manufacturers and their insurers. Indeed, behind each of the actual and potential defendants in every DES case stands in uneasy harness a complex network of primary, excess and reinsurance carriers. At present, it is far from determined how the costs of defense and indemnity are to be divided between insurer and insured under the standard commercial liability policy; coverage disputes between them have increased

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> cents of the plaintiff's dollar goes to lawyers too. This means that on the average it takes 77 cents in legal costs to deliver 65 cents to the victim, not even counting the cost to the government of running the show or the time contributed by people drafted for jury duty. . . . And like a traveling road show, the same lawyers and the same hired experts will litigate the same issues at equivalent cost dozens, or even hundreds, of times around the country before the DES saga is over. The victims will get thousands; the lawyers will get millions.

Of course, neither the Interagency Task Force Study nor the most recent systematic analysis of the substantial costs of product liability claims — the Insurance Services Office, Product Liability Closed Claim Survey: A Technical Analysis of Survey Results (1977) — reflects the vastly increased costs imposed by the adoption of the market share rule in 1980.

[2] *See* Swine Flu Act of 1976, 90 Stat. 1113 (amending 42 U.S.C. § 247(b)), insulating drug companies from products liability claims in order to insure production of the vaccine. *See generally Ducharme* v. *Merrill-National Laboratories,* 547 F.2d 1307 (1978), *cert. denied,* 439 U.S. 1002 (1978). Similar episodes are certain to arise with other drugs.

at a vast rate in the last several years without clear resolution.[3] The costs that will be imposed may be borne in some manner by insurers and manufacturers in the first instance, but in the end they constitute little more than dead weight social losses. The modern revolution in products liability law has shown that it is false and naive to assume that the institution of insurance can handle whatever distribution of risks the courts are prepared to create. *E.g., Thibault* v. *Sears, Roebuck & Co.,* 395 A.2d 843 (N.H. 1978). These dislocations will not be confined to the insurance and pharmaceutical industries, as market share liability is extended to yet other contexts — be it aspirin or aluminum wire — unless it is checked at the outset.[4] The sheer financial magnitude of these cases requires that this Court consider the important legal issues presented now. *Mercantile National Bank* v. *Langdeau,* 371 U.S. 555, 558 (1963).

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[3] *See, e.g., Insurance Company of North America* v. *Forty-Eight Insulations, Inc.,* 451 F. Supp. 1230 (E.D. Mich. 1978) (proration with insured participation), *appeal pending,* Nos. 78-1322/23/24/25/26 (6th Cir.); *Emons Industries, Inc.* v. *Liberty Mutual Fire Insurance Company,* 481 F. Supp. 1022 (S.D.N.Y. 1979) (proration without insured participation); *American Motorists Insurance Co.* v. *E.R. Squibb & Sons, Inc.,* 406 N.Y.S.2d 658 (Sup.Ct. 1978) (date of first manifestation controls). Both *Emons* and *American Motorists* are DES cases, the first involving a distributor, and the second a manufacturer.

[4] Immediately after *Sindell* was decided, plaintiffs' attorneys in California and other states began filing new suits and amending complaints in suits previously filed, alleging "market share" liability in cases involving other products. The National Law Journal, April 7, 1980, at 3; *Id.,* August 18, 1980, at 1. Commentators have characterized these suits as a "tidal wave" and "tip of an iceberg." J. Henderson, *Products Liability, DES Litigation: The Tidal Wave Approaches Shore,* 3 Corp. L. Rev. 143, 147 (1980); Comment, *DES and a Proposed Theory of Enterprise Liability,* 46 Fordham L. Rev. 963, 1007 (1978).

STATEMENT OF THE CASE

DES, the synthetic estrogen involved in this litigation, was first developed by British medical investigators in 1938. From the outset the formula for the drug was left in the public domain. Three years later, in 1941, a number of American drug manufacturers obtained approval from the Food and Drug Administration ("FDA") to produce DES for a variety of uses unrelated to the prevention of miscarriages in problem pregnancies. In 1947, after further review, FDA approved DES as safe for the prevention of miscarriages as well. Owing to the drug's widespread use and acceptance within the medical profession, FDA removed DES from the list of "new drugs" in 1952. Thereafter, any technically qualified drug manufacturer could produce DES without further testing or having to submit any new data to the FDA. From 1947 to 1971, DES was in wide and continuous use for the treatment of problem pregnancies and was produced by an estimated 200 to 300 national and regional manufacturers.

When in 1971 a correlation was found between the ingestion of DES by pregnant women and the occurrence in their daughters of a rare type of cancer (clear cell adenocarcinoma), FDA banned the drug for use in the prevention of miscarriages (but not for other purposes). It was subsequently established that DES is highly correlated with the appearance of a relatively benign non-cancerous condition, adenosis, which is the basis for most DES suits.

The 10-20 year gap between time of ingestion of DES by mothers and the manifestation of any harmful condition in daughters has made it difficult, and frequently impossible, for a DES daughter to identify the manufacturer of the DES taken by her mother. Because

of the two levels of distribution (distributor and retailer) between the various defendants and the individual plaintiffs, it is virtually impossible for a given defendant to show that its DES has *not* caused the injuries in question. Confronted with this unique situation, the California Supreme Court did not purport to abandon the causation requirement as it applies to product identification. It did, however, adopt a novel and unprecedented theory of proof (nowhere argued for by the plaintiff in her brief) based upon a student comment in the Fordham Law Review, *DES and a Proposed Theory of Enterprise Liability,* 46 Fordham L. Rev. 963 (1978). The stated purpose of the market share rule is to hold each defendant responsible, within rough limits, for that amount of damages that it would be called upon to pay if perfect product identification by source were possible. Appendix A to Petition of Abbott Laboratories ("App.") at A26.

This case therefore involves the procedural due process question of whether, with a causation requirement in place, California can adopt a mode of proof that is utterly inconsistent with its own stated objective. The challenge here is not to the use of presumptions as such. Instead, it is to an *unreasonable* presumption that will embroil the courts, both state and federal, in endless and wasteful litigation.[5]

The applicable portions of the market share rule are as follows:

> . . . we hold it to be reasonable in the present context to measure the likelihood that any of the defendants supplied the product which allegedly injured

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[5] *See, e.g., Payton* v. *Abbott Labs,* 83 F.R.D. 382 (D. Mass. 1979).

> plaintiff by the percentage which the DES sold by each of them for the purpose of preventing miscarriage bears to the entire production of the drug sold by all for that purpose. . . . .
>
> If Plaintiff joins in the action the manufacturers of a substantial share of the DES which her mother might have taken, the injustice of shifting the burden of proof to defendants to demonstrate that they could not have make the substance which injured plaintiff is significantly diminished. While 75 to 80 percent of the market is suggested as the requirement by the Fordham Comment (at p. 996), we hold only that a substantial percentage is required.
>
> . . . Each defendant will be held liable for the proportion of the judgment represented by its share of that market unless it demonstrates that it could not have made the product which caused plaintiff's injuries. . . . Once plaintiff has met her burden of joining the required defendants, they in turn may cross-complain against other DES manufacturers, not joined in the action, which they can allege might have supplied the injury-causing product.

App. A25-A26.

REASONS FOR GRANTING THE WRIT

I. The Market Share Rule Is An Irrational And Arbitrary Means Of Product Identification

The market share rule is subject to the same standards of due process as California legislation. *Chicago, Quincy and Burlington R.R.* v. *Chicago,* 166 U.S. 226, 241 (1897). *See also New York Times* v. *Sullivan,* 376 U.S. 254 (1964). In the first instance, the rule is irrational and arbitrary. Its basic premise is that the mode of proof adopted will not place upon each defendant

burdens above and beyond those that it could be properly made to bear if perfect product identification were in fact possible: "Under this [market share] approach, each manufacturer's liability would approximate its responsibility for the injuries caused by its own products." App. A26. The rule betrays that premise in three respects:

First, it imposes enormous additional litigation costs on each defendant.

Second, it provides no mechanism to insure that the admitted errors in individual cases will cancel themselves out in the long run.

Third, it establishes a systematic bias against defendants by unfairly requiring them to bear all of the alleged losses caused by other manufacturers not before the court.

Each point requires separate consideration.

A. The market share rule imposes enormous additional litigation costs upon defendants

The California Supreme Court states its market share rule as if only damage awards are to be taken into account. Its view in essence is that defendants are indifferent as to whether they defend 100 percent of ten cases or one percent of each of 1,000 cases. Nothing could be further from the truth. The rule ignores the pervasive impact of transactions costs. It compels defendants with tiny shares to defend themselves on the merits of each DES case. These litigation expenses are deadweight losses from a social point of view, and they are wholly uncompensated losses to the individual defendants. California cannot insist that its rule imposes no addi-

tional liabilities upon defendants when their litigation costs may well exceed any damage payments.

One cause of these added costs is that a unique market must be constructed for each individual case. One market will be appropriate for plaintiffs born in 1950; another for those born in 1951, and so on. The composition of each will vary with the entry and exit of different firms. Likewise, a different geographical market will have to be established for each plaintiff, owing to the different percentages of sales at each particular place at any given time. One market will be applicable for women born in Los Angeles (or some part thereof); quite another for those born in Sacramento; and still another for those born out-of-state.[6] In each geographical market, DES was sold in different dosages, at different prices, for different purposes. All that can be said, when these and other difficulties are multiplied over thousands of plaintiffs and hundreds of defendants — each with multiple insurers — is that California had made an expensive antitrust-type inquiry a prerequisite to a tort action. *Cf. Illinois Brick Co.* v. *Illinois,* 431 U.S. 720, 737-38 (1977).

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[6] In the companion California case *(Rogers)*, plaintiff's mother allegedly took DES in Chicago. One of the defendants in *Abel* v. *Eli Lilly & Co.*, 289 N.W. 2d 20 (Mich.App. 1980), distributed DES only in two cities in Michigan. Census figures report that over half the women living in California were born outside of the State. In these cases, the California court would be imposing the market share theory to conduct — and a "market" — having no relationship to California at all. And how is the market to be determined when the mother moved during pregnancy?

B. Under a market share rule the errors in individual cases will not be canceled out in the long run

The California court also insisted that the admitted errors in the individual cases would cancel themselves out in the long run. App. A25. The proposition is simply false. Consider these complications.

1. Many potential defendants will be regional manufacturers who will not be amenable to jurisdiction in California. *World-Wide Volkswagen Corp.* v. *Woodson,* _____ U.S. _____, 100 S.Ct. 559 (1980). Further, there is no guarantee that other states will adopt California's market share rule. Since these additional parties will not be bound by collateral estoppel, the possibility of third party actions cannot "even out" the losses in the long run. The rule presupposes the existence of third party actions that may not be available at all.

2. Damage awards in cases with identifiable defendants cannot be coordinated with awards under the market share rule. For the rule to have any claim to legitimacy, the manufacturer must be entitled to credit for damages paid in cases where it was identified as the supplier of the product that allegedly caused plaintiff's harm.[7] Without such a credit, then the basic premise of *Sindell* — that over time a manufacturer's overall liabili-

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[7] It is not possible to ignore the problem by assuming that in the long run specific identification will be made on a random basis. In *Abel* v. *Eli Lilly Co.*, 289 N.W.2d 20 (Mich.App. 1980), a large portion of the identified claims were against one manufacturer who supplied the particular clinic that had treated many of the DES mothers in question.

ty will approximate the liability it would have were it sued individually — is destroyed. Conversely, if a defendant is subjected to market share liability in one suit, followed by an individual judgment in a second suit, there must be some form of retroactive reallocation of the amount paid in the first suit, based upon the amount awarded in the second. How a judgment exonerating defendants in California or a particular defendant in New York, for example, bears upon these computations raises even more insoluble due process questions. Such a reallocation or continuous running recomputation would obviously be objectionable from the standpoint of a given defendant, not to mention the precepts of judicial finality.[8]

3. It is common knowledge that the amounts awarded can vary enormously among juries, even in the same state or the same district. Judicial review of jury awards is not strict and certainly does nothing to eliminate these regional and local variations. The theory of *Sindell* at its best is that each defendant must pay part of an award that he does not owe in order to escape part of an award that he owes to someone else. Yet that theory is rendered sterile when the burdens imposed and the benefits received vary enormously and unpredictably from case to case. No judicial pronouncement is able to make a $100 liability equal to a $10 benefit, or vice versa.[9]

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[8] The procedure resembles the "fluid-class recovery" condemned in *Eisen* v. *Carlisle & Jacquelin*, 479 F.2d 1005, 1018 (2d Cir. 1973), *aff'd on other grounds*, 417 U.S. 156, 172 n.10 (1974), as "fantastic" and a clear "unconstitutional violation of the requirement of due process of law."

[9] Nor does the problem end here. How are settlements to be accounted for? What consideration is to be given to the fact that some states permit punitive damages and some do not and that some juries may award them while others may not? What happens when each defendant seeks contribution in separate actions against each possible third party?

C. The market share rule contradicts its own stated objective by making defendants who constitute a "substantial" portion of the market pay for all losses causes by all manufacturers

A third defect in the market share rule does not depend upon matters of procedure and evidence, but is inherent in the statement of the rule itself. As articulated, the rule makes a "substantial" portion of the market pay for all losses of all plaintiffs. Where *any* DES manufacturers are not joined as named defendants, the named defendants are necessarily subjected to additional burdens that would not fall upon them if the source of each plaintiff's DES were established. If only 80 percent of the manufacturers by market share are joined in the suit, under *Sindell* they must pay 100 percent of the damages. And so too with 50, or even 20 percent. (This clearly is how the rule is to apply, otherwise there would be no need for third party actions.)

The result is therefore flatly inconsistent with *Sindell's* own premise. If 80% of the DES producers by market share are joined in a suit, only one of two conclusions is *in principle* proper: *Either* 80% of the plaintiffs recover their full tort damages *or* 100% of the plaintiffs recover 80% of their damages — and so with the other cases. The one wholly impermissible result is the one adopted in *Sindell.* To allow all plaintiffs full recovery against the named defendants is to a moral certainty to countenance "overpayments" to plaintiffs from these defendants and their insurers — all in violation of the probabilistic foundation of the market share rule itself.

The dangers of the rule cut deeper. Suppose some of the defendants are exonerated on the merits; the remaining defendants must pay for the losses caused by

non-tortious conduct of other parties. Suppose too that some of the defendants prove insolvent; the solvent defendants pay for the wrongs of other manufacturers. Indeed, the market share rule, with joint and several liability, requires a single solvent defendant with one percent of the market to pay for all losses of all plaintiffs.

It will be said that the rule allows suits against third parties. And so it does. But this still does not meet the problem of systematic overpayment by each manufacturer even if the objections discussed above can be overcome. Third party defendants may be innocent or insolvent. But suppose they are not. *Sindell* itself affirms that these defendants are not joint tortfeasors and that they have not engaged in any concerted action. App. A15-A18. It is therefore wholly unexplained why it is incumbent upon each defendant to sue third parties instead of leaving that task to the plaintiff. Consistent with the requirements of procedural due process, a plaintiff should not be able to recover a judgment from D-1 for harms solely caused by D-2, by assigning to D-1 plaintiff's cause of action against D-2. This violation of due process is not mitigated by casting the principle into probabilistic form. If D-1 has only a 10 percent probability of having harmed the plaintiff, then it is a denial of fair procedures to hold him for 100 percent of the loss. It makes no difference if D-1 is given in exchange an action over for 90 percent of his loss against defendants D-2 through D-300.

There is apt precedent for this point of view. In *Rees* v. *City of Watertown*, 86 U.S. 107 (1873), holders of municipal bonds in default sought to impose liability upon the citizens of the municipality that issued the bonds. This Court refused to allow the suit because it

would permit the plaintiffs to hold a single citizen responsible for the *entire loss* of the community, when in truth he was bound as a taxpayer only to pay his proportionate share. 86 U.S. at 119-20. This is the precise effect of the rule in this case. By using the market share rule, the plaintiff is permitted to hold each defendant liable not merely for its proportionate share, but for the full loss in question.

The only rational and fair way that can even begin to meet these defects is to hold each defendant only for its proportionate market share — the plaintiff taking the risk of the insolvency or immunity from suit of the manufacturers not joined in the original case. But this "solution" points out the utter poverty of the *Sindell* rule itself. As each defendant now responds only for its own share, there is no reason why any two or more manufacturers would have to be joined in order to have a "substantial" share of the market before the court. In principle, a plaintiff could sue a defendant with a one percent share of the market for one percent of her losses.

This procedure would at least remove from defendants indemnity costs that they should not in principle bear, and it would eliminate the endless suits for indemnity and contributions that will otherwise arise. Nonetheless, it fails to respond to all the constitutional objections to the market share rule. Drug manufacturers will still bear the enormous costs of defending all DES actions whenever the particular supplier is not identified; they will still be put to the task of defining market shares; and there still will be every likelihood that admitted individual errors will not cancel each other out in the long run. Whether these defects are enough to condemn this rule of proportionate shares is not before this

Court, for the rule itself has not been adopted by California. Yet a discussion of its strengths and weaknesses only confirms the previous conclusion that the market share rule as announced in *Sindell* creates such an arbitrary and burdensome presumption that it cannot withstand scrutiny under the Due Process Clause.

II. The Market Share Rule Imposes Arbitrary And Unmanageable Burdens Upon The Defendants And The Courts

At a minimum, due process demands that a party have an opportunity to defend himself on the merits against any charges made against him. This opportunity must be afforded in an atmosphere that makes possible an orderly resolution of all relevant substantive matters. In short, the issue of unmanageability rises in itself to a constitutional level. For example, class action notice requirements have been found on occasion to be so onerous and complex that their employment would constitute a violation of procedural due process. *See, e.g., Eisen* v. *Carlisle & Jacquelin,* 479 F.2d 1005, 1013 n.13 (2d Cir. 1973). Likewise, the complexity of predatory pricing suits has raised the question of whether the right to jury trial, itself guaranteed by the Constitution, is overriden by requirements of procedural due process. As the Third Circuit recently noted, there are basic due process objections "[i]f judicial decisions are not based upon factual determinations bearing some reliable degree of accuracy." *In re Japanese Electronic Products Antitrust Litigation,* 1980-2 Trade Cas. ¶ 63,421 (3d Cir., July 7, 1980).

It might be argued that consolidation of common issues will be possible. The fact remains that no such coordination will be possible on the vast majority of issues. It is frightening but true that this litigation will transcend the limits of the judicial system. It may well be possible for other systems of compensation to handle the DES cases. That issue, however, is simply not presented here; nor is it precluded by any decision which reverses the decision below. No courtroom is large enough to contain the battalion of lawyers whose services will be needed if the *Sindell* decision is permitted to remain law.

III. The Court Should Determine Whether The Market Share Rule Conflicts With The National Policies Embodied In The Federal Regulation Of Drugs

The national policy is to foster the availability to the public of low cost generic or "me-too" drugs. Federal Food, Drug, and Cosmetic Act, 52 Stat. 1040 (1938), as amended, 21 U.S.C. §§ 301 *et seq; Abbott Laboratories* v. *Gardner,* 387 U.S. 136, 138 (1967). Accordingly, FDA has promulgated regulations to encourage the sale of "identical, related, or similar drugs." 21 C.F.R. §306.1(b) (1979).

The market share theory adopted by the California court directly conflicts with this policy. It imposes liability upon the large numbers of manufacturers that sold DES after FDA sanctioned it as safe for use in preventing miscarriages. *United States* v. *Rutherford,* 442 U.S. 544, 552 n.8 (1979); *Weinberger* v. *Hynson, Westcott & Dunning, Inc.,* 412 U.S. 609, 612-13 (1973).

The California court was aware of the conflict between national drug policy and state tort law. Indeed, it

rejected the plaintiff's "concerted action" theory in part because that theory gives insufficient recognition to the "pervasive role" of the federal government in the "testing and marketing of DES." App. A23. Yet nowhere does the court explain why that pervasive federal role is not undercut by adoption of the market share rule. Like the concerted action theory, the market share rule exposes all defendants to losses caused by other defendants; it is more onerous because it does so without the necessity of proving any agreement, express or implied, among the parties. The necessary conflict between federal drug policy and state tort law is in truth greater with the "market share" rule.

In *Farmers Union* v. *WDAY, Inc.*, 360 U.S. 525 (1959), this Court held that a state law rule of defamation as applied to broadcasters was in conflict with the requirements of the Federal Communications Act. The market share liability imposed in this case stands just as much "as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress" in the drug area. *Id.* at 535. The holding in *Sindell* "would either frustrate the underlying purposes" for which the generic drug provisions of federal law were enacted or alternatively impose "unreasonable burdens on the parties governed by that legislation." *Id.*

As the dissent in *Sindell* and an intermediate California court emphasized, the imposition of liability in these cases is wholly inconsistent with federal policy. App. A34-A35; *McCreery* v. *Eli Lilly & Co.*, 87 Cal.App. 3d 77, 86, 150 Cal.Rptr. 730, 736 (1978). Congress has entrusted the administration of national drug policy — and its purpose of fostering the public's interest in "drugs that are useful in the prevention, control, or treatment of illness," *Weinberger* v. *Hynson,*

Westcott & Dunning, Inc., 412 U.S. 609, 639 n.2 (1973) (Powell, J., concurring) — to a centralized federal agency, the FDA. "Congress has chosen the FDA to be the decision maker in this area, and its judgments in approving a drug as safe for use must be beyond private scrutiny and litigation." *Gray* v. *United States,* 445 F. Supp. 337, 340 (S.D.Tex. 1978). The market share rule frustrates this policy.

CONCLUSION

The market share rule represents a serious threat to the system of judicial administration in the United States and to the national policies embodied in the federal regulation of drugs. The Due Process Clause protects litigants and the integrity of the judicial process from the artificial, unreliable and unworkable presumptions and the awesomely complex litigation that the market share rule must inevitably spawn. Federal drug legislation and regulation protect the distribution of drugs from the unwarranted intrusions of a state tort system.

The petitions for a writ of certiorari should be granted to vindicate both of these vital interests.

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